UW MEDICINE INFORMED CONSENT MANUAL

Department: Health Sciences Risk Management
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For the current version of this manual, please see:
https://intranet.uwmedicine.org/BU/hsrisk/Pages/Resources.aspx.

POLICY

A patient (or his/her legally authorized surrogate) has a right to determine what happens to his/her body while receiving health care. This right is exercised through the informed consent process.

Please refer to your entity's informed consent policy for a brief overview of informed consent requirements at your entity:

1. Harborview Medical Center: APOP 115.4
2. Hall Health Center: See UWMC APOP
3. Northwest Hospital and Medical Center: See UWMC APOP
4. University of Washington Medical Center: APOP, Special Consent for Surgical or Invasive Procedures
5. UW Medicine Neighborhood Clinics: See UWMC APOP

This manual consists of commonly asked questions and answers about informed consent. The answers summarize and interpret information about state and federal law and accreditation requirements, as well as UW Medicine policy on various aspects of informed consent that are not directly addressed by laws and other external requirements. For example, state law governs the issues of surrogate decision-maker priority lists and procedures to which surrogates may not consent, while UW Medicine policy governs the list of procedures for which a signed consent form is required.

In this manual, we intend to clarify and provide additional guidance about the consent process as it relates to patients to UW Medicine entities and to Licensed Independent Practitioners (LIPs). A robust informed consent process contributes to patient satisfaction and safety in addition to helping ensure compliance with state, federal, and accreditation requirements.

This manual is designed to provide accurate guidance with respect to select subject matters regarding informed consent. It is provided with the understanding that no author or editor is engaged in rendering legal or other professional services.

Please forward more detailed questions and report any broken links to Health Sciences Risk Management at (206) 598-6303 or hsrmhelp@uw.edu.

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WHY WE OBTAIN AND DOCUMENT CONSENT

1. Why should I be concerned about informed consent?

Individual autonomy is a cornerstone of our provision of healthcare. Under the law, a competent adult must give his/her own consent for health care. Washington state laws, federal regulations, Joint Commission standards, and standards for patient safety organizations such as Leapfrog, also set forth requirements for informed consent.

A robust informed consent process is one aspect of practitioner-patient communication. It contributes to patient safety, protects health care professionals from liability for breach of informed consent obligations, and may protect health care professionals from allegations of medical malpractice due to patient dissatisfaction, which are very often triggered by poor communication.

The best overall way to conceptualize "informed consent" is to remember that informed consent is a process, not a piece of paper. What would you, as the health care professional, want your own family member to know about this procedure or treatment?

2. What's required under Washington state law?

A health care provider in Washington is required to inform the patient of *material facts* relating to the treatment and ensure the patient was fully aware and informed of these material facts. If the patient (1) is not fully informed, (2) is harmed during care, and (3) can prove a reasonable person would not have consented to care if they had been fully informed, the health care provider can be sued for professional malpractice.

If there is no evidence of a consent discussion or signed consent form, a health care provider can be liable for medical battery. In this case, any complication of care is compensable, even if the harm is due to a recognized complication.

A health care provider is also liable if the provider promised the patient the specific complication would not occur.

See further detailed discussion below about material facts, etc.

RCW 7.70.030; 7.70.050

3. What's required by the Center for Medicare and Medicaid Services (CMS)?

The Center for Medicare and Medicaid Services (CMS), is a federal agency that imposes certain "Conditions of Participation" on hospitals in order to continue their eligibility to receive Medicare/Medicaid funding, which is critical to a hospital's survival. These "CoPs" include the following criteria for informed consent:

Hospitals must develop policies about the following:

- Who may obtain the patient's informed consent;
- Which procedures require informed consent;
- The circumstances under which the procedure is considered an emergency, and may be undertaken without an informed consent;
- The circumstances when a patient's representative, rather than the patient, may give informed consent;
- The content of the informed consent form and instructions for completing it;
- The process used to obtain informed consent, including how informed consent is to be documented in the medical record;
- Mechanisms that ensure that the informed consent form is properly executed and is in the patient's medical record prior to the procedure (except in the case of emergency);and
- If the informed consent process and informed consent form are obtained outside the hospital, how the properly executed informed consent form is incorporated into the patient's medical record prior to the procedure.

When consent forms are used, they must include these elements:

- Name of the hospital;
- Name of the specific procedure or other type of medical treatment;
- Name of the "responsible practitioner" performing the procedure or administering the treatment;
- Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's legal representative;
- Signature of the patient or the patient's legal representative; and
- Date and time the informed consent form is signed by the patient or the patient's legal representative.

CMS also advises that a "well-designed informed consent process" includes discussing the following with the patient:

- A description of the proposed procedure, including the anesthesia to be used;
- The indications for the proposed procedure;
- Material risks and benefits for the patient related to the procedure and anesthesia, including the likelihood of each;
- Treatment alternatives, including the attendant material risks and benefits;
- The probable consequences of declining recommended or alternative therapies;
- Who will conduct the procedure and administer the anesthesia;
- Whether physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the procedure, in accordance with the hospital's policies. Important tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines.[1]

[1] For surgeries in which residents will perform important parts of the procedure, CMS recommends discussing the following:

The informed consent process may not be complete until surgeons from multiple teams and the anesthesia provider are all able to discuss their respective procedures with the patient.

Revisions to the Hospital Interpretive Guidelines for Informed Consent, CMS Survey/Certification Memo 07-17, 4/13/2007

4. **What if the "responsible practitioner" changes?**

If there is a change in the "responsible" practitioner (usually the attending physician), after the consent form is signed, the patient/patient's representative should be informed to ensure his/her agreement with the substitution. A replacement consent form is not required if the form has already been signed; however, the discussion about the change should be noted in the record.

If there is a reasonable chance a substitution will be necessary when the consent form is signed, the discussion should include this possibility and the consent form can document specific information about the potential substitution. For example, 1-2 other potential attending names could be listed. Although it is acceptable to use a generic "team" description when discussing resident/fellow participation, the responsible attending should always be clearly identified.

5. **What's required by the Food and Drug Administration (FDA)?**

In addition to requiring informed consent for human subjects participating in drug and device research (see 66, below), the FDA imposes some informed consent requirements and/or recommendations regarding prescription of some approved drugs. See 19, below.

6. **What's required by The Joint Commission (TJC)?**

The Joint Commission's accreditation standards for patient rights require the provider to discuss the following aspects of informed consent with the patient:

- Nature of the proposed care, treatment, services, medications, interventions, or procedures

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- That it is anticipated that physicians who are in approved post-graduate residency training programs will perform portions of the procedure, based on their availability and level of competence;
- That it will be decided at the time of the procedure which residents will participate and their manner or participation, and that this will depend on the availability of residents with the necessary competence; the knowledge the operating practitioner/teaching surgeon has of the resident's skill set; and the patient's condition;
- That residents performing surgical tasks will be under the supervision of the operating practitioner/teaching surgeon.
- Whether, based on the resident's level of competence, the operating practitioner/teaching surgeon will not be physically present in the same operating room for some or all of the surgical tasks performed by residents.
- Whether, as permitted by State law, qualified medical practitioners who are not physicians (e.g., ARNPs) will perform important parts of the procedure or administer the anesthesia, and if so, the types of tasks each type of practitioner will carry out; and that such practitioners will be performing only tasks within their scope of practice, for which they have been granted privileges by the hospital.

- Potential benefits, risks, or side effects, including potential problems that might occur during recuperation
- The likelihood of achieving the patient's treatment goals
- Reasonable alternatives
- Relevant risks, benefits, and side effects related to alternatives including the possible results of not receiving care, treatment and services
- Any limitations on the confidentiality of information learned from or about the patient.[2]

Joint Commission Accreditation Manual for Hospitals, Standard RI.2.40

HOW WE OBTAIN AND DOCUMENT CONSENT

7. What about non-hospital practice settings?

For continuity of care and efficiency, the guidance in this manual applies to all UW Medicine care settings. All UW Medicine policies and guidance regarding informed consent incorporate CMS and TJC requirements to ensure compliance for UW Medicine's hospital-based programs.

8. What is a "material" fact or risk?

Washington law defines a "material fact" as one "to which a reasonably prudent person in the position of the patient or his representative would attach significance to in deciding whether or not to submit to the proposed treatment."

Material facts include the following:
- The nature and character of the treatment
- The anticipated results of the treatment
- The recognized possible alternative forms of treatment
- The recognized serious possible risks, complications, and anticipated benefits involved in the treatment and in the recognized possible alternative forms of treatment, including non-treatment.

The provider need not discuss every possible risk associated with the treatment. "Material" risks must be discussed. Washington case law suggests that a risk with a very small reported incidence (from .002% and possibly up to 0.75%) may not be material "as a matter of law." CMS, however, describes "material risks" as including risks with a high degree of likelihood but a [generally] low degree of severity (e.g., bleeding), as well as those with a low (or even very low) degree of likelihood but high degree of severity (e.g., death). Accordingly, consider the severity of the risk against the incidence when trying to determine which risks to discuss with the patient. Ultimately, the decision about which risks to discuss with a patient is a matter of clinical judgment. A good rule of thumb is to discuss those risks that you would want your own family member to know about.

[2] At UW Medicine, matters related to confidential information handling would be covered in our Notice of Privacy Practices, so this topic is not specifically mentioned in UW Medicine consent forms. It is not part of "informed consent" under Washington state law.

RCW 7.70.050, Ruffer v. St. Cabrini Hospital, 56 Wn. App. 625, 632-33, 784 P.2d 1288 (1990), citing Mason v. Ellsworth, 3 Wn. App. 298, 474 P.2d 909 (1970).

9. Is a potential overlapping procedure a material fact?

When considering the "nature and character" of the treatment as a "material fact," consider what facts about the care to be delivered might be significant to a reasonable patient. This can include the possibility of an overlapping procedure, the extent of resident or other trainee involvement in the procedure, or a surgeon's particular historical outcomes in similar patients.

UW Medicine requires that the potential of an overlapping procedure and the identity of the potential covering attending surgeon be discussed with the patient as part of the informed consent process.

10. Who is a "health care provider" for consent purposes?

The Washington law that requires "health care providers" to obtain informed consent is the same law that governs medical malpractice actions against "health care providers." Although the overall law defines the term "health care provider" broadly, a Washington court has held that for informed consent purposes, "health care provider" means only a physician. This holding is in an older case, and today would be likely to be extended to other licensed independent practitioners (LIP).[3]

The court's rationale for this holding was that it would be more disruptive than beneficial to patients if a hospital or its employees had a duty to intervene in the independent physician/patient relationship.

Alexander v. Gonser, 42 Wn. App. 234, 711 P.2d 347 (1985)

11. May a resident "consent" the patient?

Although it is common to refer to "consenting," the patient, it is preferable to think of obtaining or securing informed consent from the patient. Informed consent is ideally an interactive process where the patient is an important participant. It is not a process that is inflicted on the patient and where the patient is passive.

Resident physicians may appropriately obtain informed consent because they may engage in the practice of medicine under Washington law. The relevant attending physician, however, also retains an informed consent obligation when his or her resident undertakes the consent process with the patient.

RCW 18.71.030

[3] The obligation also may be extended to non-independent healthcare professionals when they function as performing providers for a procedure (e.g., RNs inserting PICC lines.)

12. May a nurse obtain informed consent?

In most situations, the RN is not functioning in the role of performing or ordering provider for a particular procedure. Accordingly, it is not generally appropriate for the RN to undertake the consent process in a primary role. There are some exceptions. When an RN inserts a PICC line independently, for example, the RN could discuss consent with the patient and complete the necessary form. The ordering provider would still be responsible for consent.

The RN may undertake educational aspects of the consent process that are suitable for delegation (see 14, below). Again, the relevant attending physician is still responsible for the consent.

13. May an advanced practice nurse or physician's assistant obtain informed consent?

ARNPs are licensed independent practitioners under Washington law, and as such, may (and are obligated to) undertake the consent process in situations where they are the ordering or performing provider for the procedure. In other situations, they may undertake delegated portions of the consent process as described below. PAs are not independent practitioners under Washington law, but may undertake delegated portions of the consent process as described below; in addition, they may occasionally function in a performing provider role as described above for RNs.

RCW 18.79.050, WAC 246-840-300, RCW 18.71.030

14. May any portions of the informed consent process be delegated?

As noted above, the attending physician/performing provider may delegate some of the education functions as well as the actual signing of the consent form, but only to another Washington state licensed health care professional whose scope of practice would include the delegated functions. Appropriate delegates may include residents, ARNPs, PAs, or RNs;[4] consent functions may not be delegated, for example, to Patient Care Coordinators or Medical Assistants. It is highly recommended that the attending physician personally conduct at least part of the consent discussion with the patient, especially to ascertain whether the patient has any questions. The primary performing provider for any procedure/ treatment is ultimately responsible for the informed consent, even if portions of it are delegated.

RCW 18.79.260 (describes general scope of practice issues associated with delegation)

15. How should I document informed consent?

If the treatment or procedure you are proposing requires a signed consent form (see 17, below), you should use and have the patient sign the appropriate "core consent" form for the treatment from the following list:

- Special Consent for Procedural Treatment, UH0173

[4] As noted above, it would be appropriate to delegate signing the consent form as the "health care professional" to a PA or RN if they were the performing provider.

    - Used for surgical and other "invasive" procedures. This form includes consent for anesthesia and blood products.
- Special Consent for Anesthesia/Sedation, UH2227
    - Used for consent to anesthesia or sedation only. Designed to be used when the procedure itself (e.g., MRI) does not require a signed consent. This form also may be used as separate anesthesia consent for an invasive procedure at the discretion of the anesthesia provider.
- Consent for Transfusion of Blood or Blood Components, UH1148
    - Used for blood administration not associated with a procedure.
- Refusal and/or Partial Consent for Blood/Blood Components, UH2063
    - Used for blood refusal or partial consent (i.e. selected components).
- Special Consent to Medical Care – Treatment or Testing, UH2224
    - Used for "medical" treatment and testing. This form is designed for "non-invasive" treatment. Simply piercing the skin does not mean a treatment is "invasive."
    - When determining whether to use this form (UH2224) or UH0173 (above), you would elect this form (UH2224) if (1) the primary risk arises from a substance/ medication used in the treatment as opposed to from the access/administration process itself, and (2) there is no anesthesia or potential blood product involvement.
    - Examples of use for this form would be high-risk medications (including injectable medications and contrast material), immunizations, and HIV testing.
    - This form should not be used for blood consent.
- Refusal of Treatment, UH2225
    - Used for general refusal of treatment. See discussion in 62, below.

The Emergent Treatment Confirmation, UH2226, is not a consent form, but is signed by the attending physician and a second physician to document clinical agreement that there is an emergent need to proceed with treatment when express consent cannot be obtained. See 39, below. This form is not mandatory, but should be completed before the treatment if possible.

If the treatment does not require a signed consent form, you may document the consent discussion and the patient's or surrogate's agreement in the medical record (usually in a progress note).

You should include specific documentation about the patient's capacity, if indicated (see discussion in 30, below).

16. How do I document about my patient's specific risks and concerns?

Although the UW Medicine "core consent" forms meet all CMS and TJC criteria for informed consent, they are designed generically and do not contain procedure-specific risk/benefit documentation in the level of detail that you would normally include in your discussion with the patient or surrogate. There are different options for documenting the procedure-specific portions of your consent discussion:

- Document in a progress note

- Hand-write in the blank lines on the "core consent" form (not much space is available)
- Provide the patient with education/reference materials as part of the discussion and reference these materials on the "core consent" form. The materials should be retrievable (i.e., standardized), and if so, do not need to be placed in the medical record.
    - See discussion below about development of this type of material.
- Document the use of the teach-back method to evaluate the patient's understanding

CONSENT FORMS

17. When must I get a signed consent form?

UW Medicine requires a signed consent form for the following types of treatment/ testing:

- Surgery. Use UH0173.
- Invasive diagnostic or interventional procedures with more than minimal risk. Use UH0173.
- Anesthesia. Use UH0173 for anesthesia associated with a procedure that requires signed consent; use UH2227 for anesthesia associated with a procedure that does not require a signed consent, e.g., MRI.
- Transfusion of blood or blood components. Use UH1148 or UH2063 if applicable (partial consent/ components only).
- Radiation therapy. Use UH2224.
- Research – Human Subjects (Note that this is a completely different type of informed consent; see 67, below).
- Electroconvulsive therapy. Use UH0173.
- Conscious sedation. Use UH0173 for sedation associated with a procedure that requires signed consent; use UH2227 for sedation associated with a procedure that does not require a signed consent, e.g., MRI.

18. Do I need a signed consent form for immunizations?

UW Medicine encourages, but does not require a signed consent form for immunizations. Use of UH2224 is recommended. Informed consent is still required even though a signed form is not mandated. In situations where obtaining a signed consent form would impede the goal of accomplishing high-volume immunizations like pneumonia/flu vaccine, a checkbox or similar system for documenting that the patient received informational materials will suffice.

The critical issue around immunizations is receipt of informational materials. Federal law requires that official CDC-sanctioned vaccine information be given out for any vaccine covered by the federal Vaccine Injury Compensation Program. This information takes the form of "Vaccine Information Statements" ("VIS"), which must be given to the patient/legally authorized representative prior to vaccine administration. VIS documents must not be altered from the CDC language, except that you may add the clinic or provider's name, address, or phone number. The CDC recommends use of VIS documents for other vaccines as well, even though they may not be covered by the Vaccine Injury Compensation Program.

The CDC recommends the following two forms of documentation for vaccines:

- In the patient's record
  - which VIS was given
  - date of publication of the VIS
  - date the VIS was given
- In either the patient's record or in a permanent office log
  - name, address, and title of the person who administered the vaccine
  - date of administration
  - vaccine manufacturer
  - vaccine lot number

VIS documents are available at the CDC's website (includes VIS documents for both covered and non-covered vaccines). The CDC also has published a short fact sheet on VIS requirements.

42 USC § 300aa–26

19. Do I need a signed consent form for high-risk medications?

The FDA requires signed consent for isotretinoin (Accutane). Isotretinoin prescribers must be registered in the FDA's iPLEDGE program in order to prescribe this medication. UH2224 may be used in connection with patient information materials that meet the iPLEDGE program criteria (the FDA's information sheet is recommended).

For some other drugs, the FDA and/or manufacturer recommends written informed consent (e.g., Erythropoetin Stimulating Agents). UH2224 may be used to satisfy this requirement. Specific patient information materials are also recommended. Other drugs require special enrollment/consent documents to be completed and provided to the manufacturer (e.g., Tysabri [natalizumab]). A copy of these special documents may be placed in the medical record as documentation of consent in these cases.

Otherwise, UW Medicine encourages, but does not require a signed consent form for high-risk medications, such as chemotherapeutic agents and for the long term use of corticosteroids. Use of UH2224 is recommended. As with vaccines, informed consent is required even though a signed form is not mandated. There are specific laws requiring documentation of attempts to obtain informed consent for administration of antipsychotic medications to involuntarily committed patients. See discussion of antipsychotic medications below in 60, section 6. You also may wish to obtain a signed consent for contrast media with a significant risk of potentially serious reaction.

20. Do I need a signed consent form for HIV or other sensitive testing?

Washington does not specifically require documentation of written or verbal consent for HIV testing by statute. UW Medicine encourages, but does not require, a signed consent form for HIV and other sensitive testing. Use of UH2224 is recommended. Providers should only order tests of any kind, but specifically sensitive tests, when there are appropriate indications. Pre and post-test

counseling and education requirements are in effect and reflected in WAC 246-100. Those elements should be documenting in the patient's medical record.

21. Do I need a signed consent form for medical use of marijuana?

UW Medicine care providers may not prescribe marijuana treatment under federal law, so a signed consent form is not required and would not be or appropriate. You may, if you wish, complete standardized documentation for your "qualified" patients who wish to avail themselves of state law protections regarding medical use of marijuana. This documentation consists of a physician statement about the patient's status as a "qualified" patient, and an understanding/agreement document that the patient signs regarding his/her status and obligations under state law. See UWMC APOP 80-15; HMC APOP 80-15 ("Healthcare Professionals Authorization of Medical Marijuana").

22. Do I need a signed consent form for "off-label" use of medications or devices?

If an FDA-approved medication or device is being used for a non-approved indication ("off-label use"), any material risks of the treatment should be considered and discussed with the patient, if appropriate. These discussions should be documented in the medical record. If the risks are beyond minimal, consider the use of a signed consent form. If the medication or device is part of a clinical trial, see 66, below.

23. Can I use a "bundled" consent for ICU admissions or an "ongoing" consent for multi-step procedures?

UW Medicine does not provide forms for "bundled" consent. If you anticipate an ICU patient may need a specific procedure in the future (e.g., lumbar puncture, arterial line), you may choose to provide the patient or patient's surrogate decision-maker with education materials about the procedure in advance. In order to obtain consent for the procedure when it is indicated, you should inform the decision-maker of the patient's specific risks, benefits, and alternatives at the time of the procedure and get a signed consent form. This will be easier if you have provided the bulk of the education in advance.

You also may use one consent form to cover multiple-step procedures (e.g., successive wound debridement) or a series of treatments (e.g., chemotherapy or blood product administration). Be sure to include either on the consent form or in your note documenting the consent discussion how many treatment episodes and/or what period of time will be needed if known (if not known, describe what is anticipated). In addition, if the series of treatments occur on an outpatient basis, you will need to be sure that the consent form is locatable at each visit for verification purposes. You may need to readdress aspects of the consent based on the patient's response to treatment or other risk factors that become known during the course of treatment.

24. Do I need a separate consent form for anesthesia?

The UW Medicine "core consent" form for surgery and invasive procedures (UH0173) includes information about anesthesia. This means that the patient needs to sign only one form

memorializing what in practice are most often two separate consent discussions (one with the surgeon and one with the anesthesiologist). Whichever of these two care providers is not the provider signing the "health care professional statement" on the surgical consent form (usually the anesthesiologist) should document his/her consent discussion with the patient separately in the medical record. This is typically done on the pre-anesthesia record. The anesthesiologist may use a separate anesthesia consent form (UH2227) if he/she wishes to do so.

25. How long is a signed consent form valid?

There is no law specifying a length of time that a consent form is valid. For consent forms regarding continuing courses of treatment, the form is valid for the length of time you have indicated to the patient. The planned length for the course of treatment should be noted in the record and ideally filled in on either the "procedure" or "details" section of the consent form.

For inpatients who have "pre-signed" their consent forms, you should either obtain a new consent form or have the patient initial and re-date the pre-signed form if it has been more than 30 days (CMS requires that you re-do the history and physical after this time period). For outpatients, it is recommended that you document the patient's validation of the consent in your note if more than 30 days have elapsed between the date the patient signed the form and the date the procedure takes place (you may wish to have the patient initial and re-date the pre-signed form in this case also). If you have asked the patient to initial and re-date the form, consider also signing or initialing the form to memorialize the change.

For both continuing treatment and pre-signed consent forms, it is always advisable to "reconfirm" with the patient regarding any interim changes and to document this in the medical record.

26. When does the signed consent form need to be witnessed?

UW Medicine "core consent" forms provide a space to document a witness to the consent, but the law does not require a witness. You may wish to have the consent witnessed if you believe there may be an issue that might benefit from a witness (e.g., questionable capacity). You should have a witness for telephone consent (See 36, below). You should also have a witness if the patient is not physically capable of marking the form.

27. May the patient amend the consent form?

Certain portions of the "core consent" forms set forth UW Medicine-wide conditions of treatment that are logistically impossible or highly impractical to vary. Accordingly, a patient should not alter the pre-printed portions of the consent form, as this would potentially obligate you to carry out treatment according to the amended conditions.

Various other aspects of the treatment plan may be negotiated if both you and the patient agree. Ideally this would be negotiated ahead of time so that the initial consent form documents the agreement and does not need to be "amended."

Note that you are not obligated to provide care with which you disagree clinically. The patient has the option to refuse treatment if he/she cannot accept treatment parameters you believe are clinically necessary.

28. What if the patient can't read or write?

You should document the consent discussion in a progress note, including the fact that the form was read to the patient because the patient was unable to read the form. You should use the form if possible; have the patient either sign their name (if they are able) or mark an "X" on the signature line (print the patient's name next to the "X"). You should use the form even if a patient is not capable to marking the form due to physical limitations. You may wish to include a witness in this process (see 26, above).

29. What if I want to write a specialized consent form?

The UW Medicine "core consent" forms may not be altered. The forms are limited in number so that they can be more easily maintained and updated to remain compliant with state law, CMS, and TJC requirements. Specialized consent forms developed by individual departments/providers may be or to become non-compliant with regulatory or accreditation-required language. If you would like consent materials that are more specific to the procedures you commonly perform, the following options are available:

A. You may request a "customized" version of UH0173 for surgery/procedures or UH2224 for medical treatment. The form will be pre-printed with your procedure/ treatment name, the title of any educational materials you provide for patients related to the procedure/treatment as applicable, and, if desired, your name as the attending provider. To make this request, contact the Health Information Management for assistance. If you are using a customized version of a core consent form, please make sure the version you are using is based on the current core consent form.

B. You may prepare procedure or treatment-specific patient education materials. To do so, contact Patient & Family Education Services at UWMC (206-598-2697) or email a statement of request for assistance with patient education material to mcsos@uw.edu. They will provide you with a template for preparing your materials, and will finalize your materials in a standardized format.[5] They also will maintain your materials and archive older versions if you update your materials (so that the existing materials for a given date will be retrievable in the future if a question arises).

If you wish to use existing standardized materials from another source (e.g., CDC materials for immunizations), it is advisable to submit those to the relevant Patient & Family department as

[5] There is a large volume of existing patient education materials in both the UWMC and HMC Patient/Family departments, but most of these were not written with the consent process in mind (i.e., containing specific information about risks, benefits and alternatives). You may use these existing materials to adapt for use in the consent process. The template mentioned above contains "placeholders" for all the needed information. Be sure to tell the Patient/Family department staff that you want to prepare education materials for consent purposes so that you receive the correct template. The template is also available from Risk Management.

well for purposes of maintenance and archiving.

If you use patient education materials as described above in your consent process, you should give the materials to the patient/surrogate and reference the title on the core consent form (Note: to avoid future confusion, it is a good idea to write "[Date] [Education Packet Title]"; the applicable date will be in the footer of the packet as prepared by the Patient and Family department). You do not need to place a copy in the medical record.

WHEN ADULT PATIENTS DO NOT HAVE CAPACITY TO CONSENT

30. How do I know if an adult patient has decision-making capacity?

An adult patient is presumed to have the capacity to provide informed consent unless they have been adjudicated "incompetent" by court order. However, a patient may be incapable of informed consent in a given situation due to the effects of injury, drugs, mental illness, or other condition.

As a practical matter, a patient must have the following to be capable of informed consent:

- Ability to understand the nature of their condition;
- Ability to understand the risks and benefits of treatment or non-treatment; and
- Ability to make a reasoned decision based upon this information. Note that the patient does not necessarily need to make what the provider would consider a wise decision, just a decision based on rational cognitive process appropriate to the situation.

The involved clinician must exercise professional judgment regarding whether s/he believes the patient is capable of informed decision-making in a particular situation. Some tools for assessing this capability include use of a "mini mental status" exam, or a psychiatric consult.[6]

RCW 7.70.065, RCW 11.88.010

31. When should I involve the surrogate decision-maker?

If the patient is clearly not able to make his/her own decisions (e.g., unconscious), you should turn to the surrogate decision-maker if available.[7] The order of priority under Washington law is discussed in 37, below. You should also turn to the surrogate if, in your clinical opinion, you do not think the patient can make his/her own decisions based on the criteria described in 30, above. If you believe the patient probably has decision-making ability but you have some questions or concerns and a surrogate is available, you may want to have the surrogate involved in your discussions with the patient (assuming the patient does not object).

[6] When requesting a psychiatric consult in this context, be sure to specify that you want an assessment of the patient's cognitive decision-making abilities and not a mental illness assessment per se. Also, your input as a provider who knows the patient is very valuable. If you find that your assessment of the patient's capacity is at odds with the psychiatric consult, a risk management consult is recommended.

[7] If there is no surrogate available, consent may be implied if there is a recognized medical emergency. See "What if there is an emergency," section 39, below.

32. What about patients with dementia who have "lucid intervals"?

It is possible for patients with dementia to have situational decision-making capacity based on the criteria described above. If you believe it is appropriate to seek a treatment decision from such a patient, you should document your assessment of this capacity at the time you are seeking the decision. If a surrogate is available and you have questions about the patient's capacity, it is advisable to involve the surrogate in the discussions.

33. What about developmentally delayed adult patients?

Determine if the patient has a court-appointed guardian; if so, the guardian must provide all consent (because this means that the patient has been deemed "incompetent" by a court of law) except for those treatments that require a court order: sterilization; electroconvulsive therapy (ECT); or mental health care, including psychotropic drugs. See 48 and 53.

Otherwise, depending upon the situation, a developmentally delayed adult may be capable of making some, most, or all of the necessary decisions for his/her health care. If you are concerned about the patient's ability to make the decision at issue, or if you believe the course of treatment may begin to invoke more complex decision-making that exceeds the patient's capacity, you may wish to involve a surrogate.

If the patient lives in a DSHS-licensed "residential habilitation center," the Secretary of DSHS is authorized to give consent if you cannot locate another surrogate decision-maker. *(RCW 71A.20.050)*

34. What about patients who have been medicated?

There is no "automatic" loss of decision-making capacity associated with receipt of sedating medication. A medicated patient's decision-making capacity will depend on several factors, including dose and route of the medication, time elapsed since administration, the patient's tolerance for the medication, and the patient's underlying medical condition. If you are seeking a treatment decision from a patient who has been medicated, you should assess the patient's decision-making capacity as described in 30, above, and document your assessment. If, in your clinical judgment, the medication has rendered the patient incapable of decision-making, you should turn to a surrogate decision-maker or wait for the patient to regain capacity. You can consult Risk Management if you are unsure whether turning to a surrogate is appropriate.

35. When do I need an interpreter?

If the patient is non-English speaking, has limited English proficiency, or uses American Sign Language, you should use a medically certified interpreter during the informed consent discussion. Federal laws require "effective communication" for these patients. While this law does not mandate a certified interpreter, failure to use an interpreter may make it more difficult to demonstrate that the communication was "effective," particularly when it involves complicated medical terminology. Patient family members over the age of 18 should only

interpret consent discussions if a qualified interpreter is not available after reasonable efforts are made to locate an interpreter. This exception should be documented in the medical record.

UW Medicine has full interpretive services, including telephone interpreters that are available during "off-hours." Contact your facility's Interpreter Services department for more information:
UWMC Interpreter Services
HMC Interpreter Services

Translated versions of some of the UW Medicine "core consent" forms also are available in three of UW Medicine's "top demographic" languages (Spanish, Russian, and Vietnamese), and are available in the Forms Repository or can be ordered with your other forms. You may give these translated forms to the patient to keep (the forms instruct the patient that they will be signing the English version, which will be kept in the medical record). Using these translated forms will assist in the consent discussion; however, you still must use an interpreter for the procedure-specific portion of the discussion.

HMC APOP 60.3: Interpretation/Linguistic Access for Persons with Limited English Proficiency or Persons who are Deaf
UWMC APOP 60-2: Effective Communication Across Language Barriers

US Department of Health and Human Services Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons

36. When may I get telephone consent?

Telephone consent is appropriate if you are unable to have an in-person discussion with the surrogate decision-maker. You must have a second person confirm the decision-maker's agreement to consent and sign as a witness. You should not record the discussion unless you have notified and received permission from all parties for the discussion to be recorded (this notification and agreement should be documented in the patient's medical record).

37. Who may make a decision for an adult patient?

Under Washington law, if an adult patient is not capable of making his/her own health care decisions, the following surrogates may decide in order of priority:

1. Legal guardian (i.e., holds a court order appointing him/her guardian of the patient's "person" (not just "estate") and authorizing health care decisions)
2. Holder of durable power of attorney (DPOA) for health care decisions (as opposed to a financial power of attorney)
3. Spouse or state-registered domestic partner
4. Adult children
5. Parents
6. Adult brothers and sisters
7. Adult grandchildren who are familiar with the patient (effective July 28, 2019)

8. Adult nieces and nephews who are familiar with the patient (effective July 28, 2019)
9. Adult aunts and uncles who are familiar with the patient (effective July 28, 2019)
10. ***At the physician's discretion***,[8] an adult who:
    a. has exhibited special care and concern for the patient;
    b. is familiar with the patient's personal values;
    c. is reasonably available to make health care decisions;
    d. is not:
        i. a physician to the patient or an employee of the physician;
        ii. the owner, administrator, or employee of a health care facility, nursing home, or long-term care facility where the patient resides or receives care; or
        iii. a person who receives compensation to provide care to the patient; and
    e. provides a declaration as described below. (effective July 28, 2019)

Note that surrogate classes four through nine, above, require unanimity. See 45, below. This is also the order in which these surrogates appear on most UW Medicine consent forms. Please also note that surrogate classes seven through ten will not be added to the statute until July 28, 2019. Because surrogate classes seven through ten are new to Washington as of this date, please consider consulting Risk Management, Ethics, and/or your Social Work team if you need to rely on these classes of surrogate.

The declaration described for surrogate class ten, above, must be signed and dated under penalty of perjury and state:

1. the facts and circumstances demonstrating that the declarant is familiar with the patient, and
2. that the declarant:
    a. is familiar with the patient;
    b. meets the requirements of surrogate class ten, described above;
    c. is a close friend of the patient;
    d. is willing and able to become involved in the patient's health care;
    e. has maintained such regular contact with the patient as to be familiar with the patient's activities, health, personal values, and morals; and
    f. is not aware of a person in a higher priority class willing and able to provide informed consent to health care on behalf of the patient.

Such a declaration is effective for up to six months and any person who knowingly provides a false declaration is subject to criminal penalties for perjury under chapter 9A.72 RCW.

If a person claims to be the patient's legal guardian or DPOA-holder, you should require the person to present a copy of the appropriate documents. No paperwork is required for a patient's family member to make health care decisions, as long as they are a member of a valid surrogate

[8] A health care provider may, but is not required to, rely on a declaration to allow an adult who is not in any other surrogate class to act as a surrogate. The health care provider and health care facility where services are rendered are immune from suit in any action, civil or criminal, or from professional or other disciplinary action when such reliance is based on the proposed surrogate's declaration.

class.[9] If an extended or non-family member holds a valid DPOA, that DPOA holder may make decisions over "lower" priority surrogates, even though those surrogates may be family members.

Before you turn to a surrogate decision-maker, you should have concluded either that the patient is not capable of his/her own decision-making or that you have concerns about that ability (see 30, above). Before turning to a "lower" priority surrogate, you should make "reasonable attempts" to obtain consent by the highest priority surrogate available. What is reasonable depends on many factors, including the exigency of the situation. Social work can usually help in trying to locate surrogates.

RCW 7.70.065

38. What if a higher priority surrogate decision-maker doesn't want to make decisions?

Surrogate decision-makers are not required to make decisions. If a higher priority surrogate declines to make decisions, you must turn to the next available priority surrogate. A surrogate cannot "authorize" a different surrogate. This includes amending a durable power of attorney (e.g., a DPOA holder may decline to serve but may not "appoint" an alternate DPOA holder). The surrogate is free to consult with someone not on the statutory list (e.g., a patient's daughter who wishes to involve a close family friend in decision-making), but the final decision must be made by the surrogate and the surrogate will sign the consent form.

39. What if there is an emergency?

If the patient is not capable of giving informed consent and a surrogate is not readily available, consent to required treatment in a recognized medical emergency is implied. A provider should not proceed with treatment in a medical emergency if the provider has knowledge of facts negating consent such as previously stated patient preference. The Medical Director, Administrator-on-Call, and Risk Management are available to consult in these situations.

RCW 7.70.050; RCW 18.71.220.

40. What constitutes an emergency?

There is no specific definition of "recognized medical emergency" in Washington law. It would clearly include treatment that is necessary to preserve life or to prevent serious disability. It also may include other types of treatment that cannot be delayed without risking unacceptable deterioration or aggravation of the patient's condition. The circumstances for proceeding without consent should be documented in the medical record and you should complete UH2226 if there

[9] You do not need to request copies of registration documents from a patient's state-registered domestic partner; you may rely on the person's representation that they are the patient's registered domestic partner just as you would rely on a person's representation that they are a patient's spouse without the need to request a copy of a marriage certificate. If a family member challenges either domestic partner or marital status, however, you should request appropriate documentation.

is time. The decision to proceed with emergent treatment is not to be considered informed consent.

41. Are there special considerations for emergency obstetrical interventions?

Obstetrics presents a unique consent situation because no matter how close to term, an unborn fetus does not have legal standing. Only maternal emergencies are considered obstetric emergencies that invoke the implied consent provisions of the law. The typical question/scenario is whether to proceed with an "emergency" Caesarean section if the mother is unable to make her own decisions. These guidelines may be helpful:

> (1) Surrogate available: The surrogate may consent to the C-section even if the indication is fetal (distress). This would be based on substituted judgment, i.e., what the mother would have wanted. If the surrogate refuses, consult Risk Management.
> (2) No surrogate available: If there are maternal indications for the C-section (abruption, placenta previa, etc.), proceed. If the indication is fetal, you may choose to proceed if there is no indication that the mother would have refused. See discussion in 63, below.

42. May I use a "two-physician consent"?

There is no such thing as "two-physician consent." A physician is not a legally authorized surrogate and may not consent for a patient's treatment. Only a patient or the patient's surrogate may consent to treatment. If you wish to proceed with treatment under the "implied consent" emergency exception described in 39, above, you should (1) document your reasoning in the medical record, and (2) complete an "Emergent Treatment Confirmation" form (UH2226), before the treatment if possible. This form is signed by the attending physician and a second physician to document clinical agreement that there is an emergent need to proceed with treatment. The second physician may be a resident. The Emergent Treatment Confirmation is not a consent form. You may use the "Emergent Treatment Confirmation" for treatment that is not imminently lifesaving or necessary to prevent significant harm, but is needed to prevent harm to the patient before an appropriate decision maker can be found or appointed by the court (see 49, below). You should consult Ethics and Risk Management before proceeding with treatment.

43. What if I discover additional procedures that need to be done while I am doing the consented-for procedure?

Consent is limited to the procedure or treatment discussed with the patient and noted on the consent form. An additional or modified consent is required for additional procedures. There is an exception if a "recognized medical emergency" occurs during the procedure; even in that case, if possible the legally authorized surrogate should be consulted, especially if the additional procedures are not life-preserving. The initial consent should not be drafted broadly enough to create "blanket authorization" for additional procedures.

44. What if I can't find a surrogate decision-maker?

If the patient is not capable of giving consent, treatment is not emergent, and no surrogate can be located, a guardian must be appointed for the patient through the judicial process. Each UW Medicine hospital has resources in place to assist with obtaining guardians. See 49, below.

45. What if the surrogate decision-makers or other people involved with the patient don't agree with each other?

If the decision-maker is in a "multiple member" surrogate group (children, parents, siblings), unanimity is required. This does not mean that if there are eight siblings and you have located only five, you need to delay treatment unduly while attempting to locate the other three siblings. Again, only "reasonable attempts" are needed.

If you are faced with a dispute between the members of the surrogate group, this can often be resolved by holding a family conference. Once the children/siblings, etc. understand that judicial intervention may be necessary if they ultimately cannot agree on a treatment decision, they typically become more motivated to agree. You may wish to obtain an Ethics and/or Risk Management consult in these cases.

RCW 7.70.065

46. What if the surrogate decision-maker is making decisions I believe are not good for the patient?

Washington law charges surrogate decision-makers with using "substituted judgment" as the preferred basis for decision. In other words, the surrogate should decide as they believe the patient would have wanted, which is not necessarily what the surrogate would choose for him/herself. If there is no evidence of what the patient would have wanted, the surrogate is charged with making a decision that is in the "best interests" of the patient. There are additional obligations that fall on parents as the surrogate decision-makers for their children (see 54, below). If you believe that a surrogate is not making appropriate decisions for the patient, you may consult Ethics or Risk Management.

RCW 7.70.065

47. When should I request an Ethics and/or Risk Management consult?

You may want to consult Ethics or Risk Management if you are faced with a difficult surrogate decision-making situation. Examples may include:

- Disputes within "multiple member" surrogate classes
- Other family-surrogate disputes
- Disputed status of a surrogate (e.g., allegations regarding marriage status)
- Staff concerns about poor decision-making by surrogate
- Patient without capacity affirmatively refusing treatment
- No surrogate available

The consults, discussions, and decisions with or concerning surrogate decision makers should be documented in the patient's medical record.

Risk Management consults should not be documented in the medical record.

HMC Administrative Policies and Procedures 80.49, Ethics Consultation
UWMC Administrative Policies and Procedures 5-66, Ethics Advisory Committee & Clinical Ethics Consultation Service

48. When do I need a court order for treatment?

A court order should be sought for treatment if the patient is not capable of giving consent, treatment is not emergent, and no surrogate can be located. This involves seeking appointment of a guardian for the patient and can take several weeks. See 49, below.

A court order must be obtained if the patient is not capable of consent and the proposed treatment is one of the following, even if there is a surrogate available:

- Sterilization (minors and adults without capacity cannot undergo this procedure without court order).
- Electroconvulsive therapy/ "psychosurgery"
- Mental health care, including psychotropic drugs (there is a completely separate judicial process for this; see 59, below).

You also may want to consider obtaining a court order when the proposed treatment is highly disfiguring (e.g., amputation). An Ethics consult is highly recommended in such situations.

If there is a surrogate or other family available but a court order is nonetheless needed for some reason, it is preferable for the surrogate/family to file the petition and otherwise take responsibility for obtaining the court order. The hospital can take that responsibility if no surrogate or family is available.

RCW 11.92.043, In re Hayes, 93 Wn.2d 228, 238, 608 P.2d 635 (1980).

49. What's the process for obtaining a court-appointed guardian to make health care decisions?

The process is initiated by filing a petition for guardianship with the local court. This may be done by the patient's family or by the hospital. It can take up to 4-6 weeks before a guardian is appointed who can actually make health care decisions, so if you believe your patient may need a guardian, it is advisable to begin the process as soon as possible.

HMC/UWMC: Social Work or the care team contacts the Attorney General's Office for appointment of special counsel.

NWH/VMC: Social Work or the care team contacts Risk Management.

Your input as the patient's health care provider will be needed, including a possible declaration for the court regarding the patient's medical condition, decision-making capacity, and need for treatment. If your patient's need is more urgent, special counsel can often expedite the process. Be sure to clearly communicate this need to the attorney handling the guardianship procedure.

A "guardian ad litem" will be appointed initially when the petition is filed; it is his/her responsibility to prepare a report to the court, which will be considered at the guardianship hearing (up to approximately 4 weeks after filing). Occasionally the court will also issue an initial order allowing interim treatment in the time pending the guardianship hearing, but this is not customary. If you believe your patient needs interim treatment, you should specifically request that the special counsel seek such an order.

RCW Chapter 11.88, 11.92

50. What's the difference between a "guardian ad litem" and a guardian?

A "guardian ad litem" (GAL) is a person (often a lawyer, but not necessarily) appointed by the court who aids the court in determining whether the patient is legally incapacitated and/or needs legal representation regarding the petition for guardianship. The GAL speaks with the patient, family, and health care team, and prepares a report for the court, but generally does not make health care decisions for the patient.

A guardian is a person who has been appointed by the court to act as an incapacitated patient's decision-maker.

RCW Chapter 11.88, 11.92

51. What about decisions to withhold or withdraw life-sustaining treatment?

These treatment decisions should be handled as with other informed consent issues. The discussion should take place with the patient if possible, and/or with the surrogate decision-maker. If the patient has decision-making capacity, he/she has the absolute right to request or refuse life-sustaining treatment, despite what may be contained in a "living will" or other advance directive. When considering end of life issues, remember that health care professionals are never obligated to provide treatment that is considered medically futile.

If the patient does not have decision-making capacity, the terms of the patient's advance directive constitute evidence of what the patient would want. These terms should be respected by the health care providers and the patient's surrogate decision-maker. While an advance directive is evidence of what the patient would want, the surrogate has the ultimate authority to make decisions regarding life-sustaining treatment. If you feel that the surrogate is acting inconsistently with the patient's wishes and/or not in the best interests of the patient (if there is no advance directive), you may wish to consult Ethics and/or Risk Management. In some cases, judicial intervention may be appropriate.

Please refer to your entity's advance directive/withdrawal of life support policies to determine when withholding and withdrawing life-sustaining treatment is appropriate.

If there is no advance directive and no surrogate, or the patient is not in a "terminal condition"[10] or "permanent unconscious condition"[11] under the terms of the Washington Natural Death Act, a court order may need to be sought before withholding or withdrawing life-sustaining treatment. You should consult Risk Management in these situations.

See
UWMC Administrative Policy and Procedure Manual 5-80: Advance Directive (Federal Patient Self-Determination Act)
HMC Administrative Policies and Procedures Policy Number 5.25 Advance Directive (Federal Patient Self-Determination Act)
DECISIONS TO WITHHOLD OR WITHDRAW LIFE-SUSTAINING TREATMENT (80.1) (UW Medicine Policy)
RCW 70.122.020, .030

52. What's the difference between a Durable Power of Attorney and an Advance Directive or "Living Will"?

A "Living Will" or "Health Care Advance Directive" is a document that expresses a patient's specific wishes regarding whether the patient wants life-sustaining treatment withdrawn or withheld. It does not designate a surrogate decision-maker but simply memorializes the patient's wishes. Under Washington law, its use is limited to situations where the patient is terminally ill or in a vegetative state. There are certain statutory requirements for Advance Directives, including who may and may not witness the document. If the patient has an advance directive or "living will", these documents can provide evidence of what the patient would have wanted. However, the documents are not consents in and of themselves except in limited circumstances. You still generally must obtain consent from a surrogate decision maker for a patient with an advance directive.

A health care Durable Power of Attorney (DPOA) is a document designating a surrogate decision-maker for health care decisions (and may also designate an alternate in case the primary surrogate is unable to serve). This surrogate is empowered to make a wide range of treatment decisions for the patient in the event that the patient is not capable of making his/her own decisions, including but not limited to decisions about life-sustaining treatment. The DPOA document must clearly state that the power of attorney specifically includes health care decision-making. It also must clearly state either that the power of attorney "shall not be affected by the incapacity of the principal," or that the power of attorney "shall become effective upon the incapacity of the principal," or similar language. Legal requirements for validity of these

[10] "Terminal condition" means an incurable and irreversible condition caused by injury, disease, or illness that, within reasonable medical judgment, will cause death within a reasonable period of time in accordance with accepted medical standards, and where the application of life-sustaining treatment serves only to prolong the process of dying.
[11] "Permanent unconscious condition" means an incurable and irreversible condition in which the patient is medically assessed within reasonable medical judgment as having no reasonable probability of recovery from an irreversible coma or a persistent vegetative state.

documents vary by state. Documents executed in Washington after January 1, 2017, must be signed and either notarized by one person or witnessed by two people who are not caregivers for the patient or relatives of the patient.

Military Powers of Attorney are governed by a different law and are exempt from state laws regarding form, substance, formality, or recording.

Consult Risk Management or the Attorney General's office if you are unsure whether the patient's DPOA is valid.

For details about Advance Directives and Durable Powers of Attorney for Health Care, see:
UWMC Administrative Policy and Procedure Manual 5-80: Advance Directive (Federal Patient Self-Determination Act)
HMC Administrative Policies and Procedures Policy Number 5.25 Advance Directive (Federal Patient Self-Determination Act)
HMC Administrative Policies and Procedures 5.78/Admin: Mental Health Advance Directives
RCW 70.122 (Natural Death Act); RCW 11.125 (Uniform Power of Attorney Act).
10 U.S.C. § 1044b (Military DPOA)

53. Are there treatment decisions that surrogates may not make?

Surrogate decision-makers are prohibited by law from authorizing the following types of treatment (see 33 and 48):

- Sterilization
- Electroconvulsive treatment/ "psychosurgery"
- Involuntary mental health treatment/psychotropic drugs—see 59, below.

A court order is needed in order to perform the above treatments on patients who are not capable of consenting for themselves. This includes minors and developmentally delayed patients, e.g., the parents of such patients cannot consent to sterilization procedures for them. A court order may also be advisable when considering amputation or other highly disfiguring procedures in a patient who cannot consent for themself.

RCW 11.92.043, In re Hayes, 93 Wn.2d 228, 238, 608 P.2d 635 (1980).

WHEN THE PATIENT IS A MINOR

54. Who may make decisions for a minor patient?

In descending order of priority:

1. Guardian/legal custodian pursuant to RCW Title 26, if any
2. Court-authorized person for child in out-of-home placement, if any
3. Parents (obtaining the consent of both parents is preferable, if it can reasonably be obtained)

4. Holder of signed authorization or DPOA from parents
5. Adult representing self to be a relative responsible for the minor's health (see kinship caregivers, below)

Special situations:

- Divorced parents: If parents are legally separated or divorced, a parent must have "decision-making authority" under the temporary or permanent "parenting plan" in order to consent for the child's health care. If a parent does not have this decision-making authority, he/she may not make any decision for the child other than those relating to emergency care. If the parenting plan designates decision-making or custody to be "mutual," or "joint," the consent of either parent is sufficient. The health care provider need not obtain a copy of the parenting plan, but may rely upon the representation of a parent that he or she possesses the health care decision-making authority. If a health care provider has notice, however, that the parents are in conflict regarding either the terms of the parenting plan or divorce decree, or consent to specific health care, the provider should obtain a copy of the parenting plan or divorce decree for interpretation.[12]
- Unmarried Parents: When the parents have never been married and/or registered with the state as a domestic partnership, only the mother may consent to health care for the child unless the father has established a parent-child relationship under Washington law.
- Non-Parental Custodians: Should have a court order demonstrating custody.
- Kinship Caregivers: May have a signed authorization from the parent(s) or may represent themselves to be a relative responsible for the child's health (see above). The health care provider may rely on this representation so long as there is no actual notice of the falsity of the statements. However, if the kinship caregiver provides a declaration signed and dated under penalty of perjury that the individual is a relative responsible for the child's health care, this kinship declaration https://www.dshs.wa.gov/sites/default/files/ALTSA/hcs/documents/22-1119.pdf is effective for up to six (6) months and guarantees immunity from civil or criminal suit based on lack of consent.
- Shelter Care/Foster Homes: The court order for placement specifies the agency or individual who has the authority to consent for the child's health care. This authority typically extends only to routine medical, dental, and psychological examination and care. The typical order also allows the agency or individual to authorize all necessary emergency care for a child. Elective or necessary non-emergency surgical care including anesthesia, requires either a natural parent's informed consent or a court order authorizing the health care provider to perform the procedures on a minor child in dependency.
- Homeless Children or Youth: A school nurse, school counselor, or homeless student liaison is authorized to provide consent for health care for a homeless student if:
    - Consent is necessary for nonemergency outpatient primary care services, including physical examinations, vision examinations and eyeglasses, dental

[12]Even a parent without decision-making authority normally should be permitted access to the child's health information except in very unusual circumstances. If you have a question in this area, contact your facility's Privacy Officer.

examinations, hearing examinations and hearing aids, immunizations, treatments for illnesses and conditions, and routine follow-up care customarily provided by a health care provider in an outpatient setting, excluding elective surgeries.
    - The patient meets the definition of a "homeless child or youth" under the federal McKinney-Vento Homeless Assistance Act, which is aimed at addressing the problems that homeless children and youth have faced in enrolling, attending, and succeeding in school.
    - The patient is not under the supervision or control of a parent, custodian, or legal guardian and is not in the care and custody of the Department of Social and Health Services.
- Refusal of Treatment: Washington law requires parents to provide necessary medical attention to their dependent children. When a minor's condition is life-threatening, and the parents or legal guardians refuse necessary treatment, a court order permitting provision of the recommended treatment may be obtained pursuant to RCW Chapter 13.34. In the meantime, hospitals and physicians are specifically authorized by statute to detain a child without the consent of "a person legally responsible for the child," if there is reasonable cause to believe "that permitting the child to continue in his or her place of residence or in the care and custody of the parent, guardian, custodian or other person legally responsible for the child's care would present an imminent danger to that child's safety." The detention is authorized whether or not medical care is required. The hospital administrator or physician detaining a child without consent under these circumstances must notify the appropriate law enforcement agency or child protective service as soon as possible, but in no case longer than 72 hours after the detention.
- Native American Children: These children may be subject to special federal and state laws. Providers should seek legal advice on situations where court orders of Indian tribes may control the custodian who may give health care consent for an Indian child. Situations may include when the patient is the subject of dependency or parental termination proceedings, in the pre-adoption process, or in proceedings for non-parental custody.

RCW 7.70.065, RCW Chapter 13.34, RCW 26.44.056; Washington State Society of Healthcare Attorneys Health Law Manual, Third Edition, Chapter 2B

55. When may minors make treatment decisions for themselves?[13]

The "age of majority" for all care in Washington is 18 years. "Emancipated minors" also may give informed consent for all their health care. The following are methods by which a minor may become emancipated:

- Married to an adult (spouse must be 18 or older).
- Age 16 and has obtained a court declaration of emancipation. A Washington driver's license or identification card will designate emancipation and should be copied for the

[13] If the decision-making right belongs to the minor, control over release of that health care information also belongs to the minor. See UW Medicine Privacy Policy COMP.103, Use and Disclosure of Protected Health Information – Minor Patients. Also, payment obligations generally do not flow to a parent who is not involved in the consent; if you have specific questions in this area, a risk management or compliance consult is recommended.

medical record. A copy of the court order is also appropriate documentation to place in the record.

- Determined by a physician or other LIP to be a "mature minor". Factors include age, intelligence, maturity, training, experience, economic independence, and freedom from parental control. Note that the minimum age may be gauged against the statutory requirement, which is 16, such that a younger age may not be deemed to signify sufficient maturity. Documentation should discuss the above factors to show the maturity of the minor. Smith v. Seibly, 72 Wn. 2d 16 (1967).

Minors also may consent to the following specific types of treatment at various ages:

- Sexually Transmitted Disease: Minors 14 or older who may have come in contact with any sexually transmitted disease or suspected sexually transmitted disease may consent to hospital, medical and surgical care related to the diagnosis or treatment of such disease without parental consent. This includes "sexually transmitted diseases" as defined under Washington law.[14] Note that the actual route of transmission in a specific case is not necessarily required to be sexual (e.g., IV drug use).
- Reproductive Care: Minors may consent to examination and treatment, including prescriptions for birth control, voluntary termination of pregnancy, or care related to pregnancy, without parental consent or knowledge. There is no articulated age; this concept is based on the constitutional right of privacy regarding reproductive rights. Use clinical judgment regarding whether to involve the parents of a very young sexually mature minor. It is always advisable to encourage minors seeking reproductive treatment to discuss this care with their parent(s).
- Substance Abuse: Minors 13 or older may consent for outpatient treatment by a certified chemical dependency treatment program without parental consent. Parental consent is required for inpatient treatment programs.
- Mental Health Treatment
    - Outpatient treatment: Minors 13 or older may consent to voluntary outpatient mental health treatment without parental consent.
    - Inpatient Treatment
        - Minors under 13 may only be admitted on the application of the parent
        - Minors 13 or older may be voluntarily admitted by application of the parent, with the written consent of the minor, or may admit self without parental consent, provided that notice is given by the facility to the minor's parent. Additional procedural steps must be followed.
- Care of own child(ren): Minor parents may make health care decisions for their children. If the health care provider believes that the minor parent is unable to make responsible health care decisions for his or her child, it may be necessary to contact Child Protective Services. A legal guardian may need to be appointed for the child patient. The parents of the minor parent, as the patient's grandparents, do not have the right to consent to the

[14] "Sexually transmitted disease" ('STD') means a bacterial, viral, fungal, or parasitic disease or condition which is usually transmitted through sexual contact, including acute pelvic inflammatory disease; chancroid; chlamydia trachomatis infection; genital and neonatal herpes simplex; genital human papilloma virus infection; gonorrhea; granuloma inguinale; hepatitis B infection; human immunodeficiency virus infection (HIV) and acquired immunodeficiency syndrome (AIDS); lymphogranuloma venereum; nongonococcal urethritis (NGU); and syphilis.

health care of their grandchild unless they have obtained a court order of custodianship or guardianship or qualify as appropriate surrogates representing themselves as the adult relatives responsible for the minor's health.

RCW 7.70.065, RCW Chapter 13.64, RCW Chapter 26.28, RCW Chapter 70.24, RCW Chapter 70.96A, RCW Chapter 71.34, WAC Chapter 246-100, State v. Koome, 84 Wn.2d 901, 530 P.2d 260 (1975)

LAW ENFORCEMENT AND CONSENT

56. What if the patient is a prisoner?

Prisoners do not lose their rights to consent to health care. The same consent requirements exist for prisoners as for other persons.

You may come across the following exceptions:

- Driver's Implied Consent law (see 57, below).
- Nonconsensual HIV testing and/or other blood borne pathogens of a sexual offender or a jail detainee under circumstances permitted by state law (this must be ordered by a public health officer).

RCW 70.24.340, .360, .370; WAC 246-100-206.

57. What about "legal blood draws" requested by the police?

Washington state law deems anyone who operates a motor vehicle to have given "implied consent" to alcohol or drug testing in connection with operation of the motor vehicle. Note that this is not informed consent for medical purposes. If the patient is unconscious, blood may be drawn without further "consent" (relying on the motor vehicle law's implied consent provision).

If the patient is conscious, the accompanying police officer must provide the person with a variety of information about the blood draw and its ramifications. Despite the motor vehicle law's "implied consent" provision, a conscious patient may refuse the blood draw. There are legal consequences with respect to criminal traffic proceedings for a person who refuses to have his or her blood drawn in these circumstances, but the refusal must be honored by a health care provider, except in the following limited circumstances, when the health care provider may draw blood at the request of law enforcement even though the patient refuses:

- If the police officer has obtained a search warrant from a judge ordering that the blood draw be made;
- If the accompanying police officer states that the patient is one of the following (this should be documented in the medical record along with the police officer's name and badge number):
    - Under arrest for vehicular homicide,
    - Under arrest for vehicular assault, or

- Under arrest for driving under the influence of intoxicating liquor or drugs resulting in an accident in which there is a reasonable likelihood that another person may die of injuries.
- And the police officer states exigent circumstances exist that have made it impossible for him / her to obtain a search warrant.

A copy of the search warrant should be included in the patient's medical record.

RCW 46.20.308.

58. What about urine or blood tests for drugs in, for example, trauma or obstetric patients?

There should be a medical indication for any diagnostic test, including blood or urine drug screening. Because of the sensitive nature of these tests, the test and its medical indications should be discussed with the patient (or the patient's surrogate) in advance. A signed consent form is not needed, but can be used at the provider's discretion. The consent discussion should be documented in the medical record.

If a patient is unable to give consent (e.g., trauma) and there is no surrogate available, you may proceed with the testing if it will inform emergent treatment (i.e., it should not be done for "evidentiary" purposes unless there is a court order or the situation meets the criteria for a "legal blood draw" as described in 57, above).

For a detailed discussion of maternal and infant drug toxicology testing, see the Guidelines for Testing and Reporting Drug Exposed Newborns in Washington State. This publication is authored by DOH and includes helpful information on maternal and infant medical indications for testing, tips for having a consent discussion with an infant's parent(s), and guidance about proceeding with testing/ administrative hold/ Child Protective Services notification when a parent refuses to consent to infant testing. Drug screening results in pregnant women may not be reported to CPS prior to birth of the infant.

UWMC MIC/NICU Department Policy: Neonatal Abstinence Syndrome;
UWMC APOP 5-1: Abuse, Neglect and Exploitation of Vulnerable Adult and Child Patients: Identifying, Mandated Reporting, and Documenting

PSYCHIATRIC PATIENTS

59. What about surrogate decision-making for mental health treatment?

A surrogate is not ordinarily authorized to consent to mental health treatment on the patient's behalf if the patient is not capable of making his/her own decision. If a patient who is not capable of making healthcare decisions requires mental health treatment, that treatment may be directed by a surrogate DPOA appointed through the patient's mental health advance directive.

A patient who executes a valid mental health directive under Washington law while competent may receive mental health treatment (and other related medically necessary treatment) under the terms of that advance directive if they are in need of mental health treatment but no longer capable of their own decision-making.

In order to be valid, a mental health advance directive must

1. Be in writing;
2. Clearly indicate that the patient intends to create a directive;
3. Be dated and signed by the patient or contain documentation that it was signed at the patient's direction in the patient's presence;
4. Designate whether the patient wishes to be able or unable to revoke the directive during any period of incapacity; and
5. Be witnessed in writing by at least two adults, containing a declaration by each that he or she personally knows the patient, was present when the patient dated and signed the directive, and that the patient did not appear to be incapacitated or acting under fraud, undue influence, or duress.

The directive may also appoint a durable power of attorney for health care. If so, it must clearly state (1) that the power of attorney "shall not be affected by the incapacity of the principal," or (2) that the power of attorney "shall become effective upon the incapacity of the principal." Other similar language may also suffice.

The directive may include any provision relating to mental health treatment or other care of the patient. These provisions might include the following:

- The patient's preferences and instructions for mental health treatment;
- Consent or refusal to consent to specific types of mental health treatment, including electroconvulsive therapy;
- Consent to admission to and retention in a facility for mental health treatment for up to fourteen days;
- Descriptions of situations that may cause the patient to experience a mental health crisis;
- Suggested alternative responses that may supplement or be in lieu of direct mental health treatment, such as treatment approaches from other providers;
- The patient's nomination of a guardian or limited guardian for consideration by the court if guardianship proceedings are commenced.

A patient who has executed a mental health advance directive, is no longer capable of decision-making, and is in need of mental health treatment, may be admitted for that treatment even if the patient refuses, as long as the following conditions are met:

- The patient elected not to be able to revoke his or her directive during any period of incapacity;
- In the directive, the patient consented to voluntary admission to inpatient mental health treatment, or authorized an agent to consent on his/her behalf;

- Prior to admission, a physician[15]
    - evaluates the patient's mental condition, including a review of reasonably available psychiatric and psychological history, diagnosis, and treatment needs, and determines, in conjunction with another health care provider or mental health professional, that the patient is incapacitated;
    - Obtains the informed consent of the agent, if any, designated in the directive;
    - Documents in the medical record that the patient needs an inpatient evaluation or is in need of inpatient treatment and that the evaluation or treatment cannot be accomplished in a less restrictive setting; and
    - Documents in the medical record a summary of the physician's findings and recommendations for treatment or evaluation.

The patient must either be discharged or detained under the involuntary treatment act no more than fourteen days after admission unless he/she has regained capacity and consents to continued inpatient treatment. Re-evaluation of the patient's capacity must take place at the following intervals:

> (1) Within seventy-two hours or when there has been a change in the patient's condition that indicates he/she appears to have regained capacity, whichever occurs first.
> (2) When the patient or his/her DPOA agent (if any) requests a re-determination of the patient's capacity (the re-determination must be made within seventy-two hours if treatment is on an inpatient basis, and within five days if treatment is on an outpatient basis).

See:
HMC Administrative Policies and Procedures 5.78/Admin: Mental Health Advance Directives
UWMC Administrative Policy and Procedure Manual 5-80: Advance Directive (Federal Patient Self-Determination Act)

RCW 7.70.068, RCW 71.32.050, RCW 71.32.060, RCW 71.32.140

60. How do involuntarily committed patients consent for treatment?

A complete explanation of Washington law on involuntary mental health treatment ("civil commitment") is beyond the scope of this manual. Relevant consent-related principles are summarized below.

(1) If a patient is brought to the emergency room, the person refuses voluntary admission, and the health care professional staff believes the patient presents an imminent likelihood of serious harm, or is gravely disabled[16] due to a mental disorder, they may detain the patient for sufficient

[15] If the admitting physician is not a psychiatrist, the patient must receive a complete psychological assessment by a mental health professional within twenty-four hours of admission to determine the continued need for inpatient evaluation or treatment.
[16] Washington law defines "gravely disabled" as a condition in which a person, as a result of a mental disorder: (a) Is in danger of serious physical harm resulting from a failure to provide for his or her essential human needs of health or safety; or (b) manifests severe deterioration in routine functioning evidenced by repeated and escalating

time to notify the designated mental health professional (MHP). The MHP may authorize the patient to be further held in custody or transported to an evaluation and treatment center. This must be done no more than six hours from the time the health care professional staff determines that an evaluation by the MHP is necessary.

(2) If the health care professional staff believes that a voluntarily admitted patient who requests discharge presents an imminent likelihood of serious harm, or is gravely disabled due to a mental disorder, they may detain the patient for sufficient time to notify the MHP. The MHP may authorize the patient to be further held in custody or transported to an evaluation and treatment center (in ordinary circumstances no later than the next judicial/business day).

(3) The MHP, after investigation and evaluation of the specific facts alleged, may take the patient, or by oral or written order cause the patient to be taken into emergency custody in an evaluation and treatment facility for not more than seventy-two hours (computation of the seventy-two hour period excludes Saturdays, Sundays and holidays; i.e., non-judicial days). After that time, a hearing must be held and a court order issued for continued detention and treatment (up to fourteen days of intensive treatment or ninety days of less intensive treatment at a time).

(4) A law enforcement officer also may take or cause such a patient to be taken into custody and immediately delivered to a crisis stabilization unit, an evaluation and treatment facility, or the emergency department hospital if the officer has reasonable cause to believe that the patient is suffering from a mental disorder and presents an imminent likelihood of serious harm or is in imminent danger because of being gravely disabled. The facility to which the officer delivers the patient in these situations may hold the patient for up to twelve hours, provided that the patient is are examined by a mental health professional within three hours of their arrival. Within twelve hours of arrival, the MHP must determine whether the individual meets detention criteria.

(5) A patient who has been involuntarily detained or admitted must, within twenty-four hours of admission, be examined and evaluated by a licensed physician (who may be assisted by a physician assistant, advanced registered nurse practitioner) and a mental health professional. The patient may then receive needed treatment even though they may not have the capacity to consent, pending the next follow-up commitment hearing and court order. A patient's refusal of treatment, however, must be honored pending a specific court order unless the situation meets one of the exceptions below. (Note that whether a patient has decision-making capacity is a separate issue from whether he/she meets criteria for mental health detention; although lack of capacity often accompanies involuntary treatment criteria, this is not always the case.)

(6) The patient may refuse antipsychotic medications at any time except during a psychiatric emergency, see 61, below. Pending a court order and/or within 24 hours of a commitment hearing, the patient may refuse all psychiatric medication (including antipsychotics). See 61, below.

(7) The patient may refuse electroconvulsive therapy pending a court order.

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loss of cognitive or volitional control over his or her actions and is not receiving such care as is essential for his or her health or safety.

(8) The patient may refuse any type of psychosurgery.

(9) The patient may not refuse "medication previously prescribed by a licensed provider" (except psychiatric medication as described above).[17]

(10) The patient may not refuse emergency life-saving treatment.

(11) The patient has a right to have a family member, guardian or other designated person receive written notice of inpatient status, and of the patient's rights as an involuntarily detained person.

HMC Inpatient Psychiatry policies and procedures related to involuntary treatment
UWMC Patient Care Services Policy & Procedures for Inpatient Psychiatry – 7N: Involuntary Detention – Referral to County Designated Mental Health Professional (CDMHP)

RCW Chapter 71.05, WAC Chapter 388-865

61. When is there a psychiatric emergency that allows providers to compel antipsychotic medication?

A psychiatric emergency exists if the patient presents an imminent likelihood of serious harm to his/herself or others, and medically acceptable alternatives to administration of antipsychotic medications are not available or are unlikely to be successful; and in the opinion of the physician, the patient's condition constitutes an emergency requiring the treatment be instituted prior to obtaining a second medical opinion. An additional concurring medical opinion approving medication should be obtained as soon as possible.[18] The medical record must contain documentation of the physician's attempt to obtain the patient's informed consent and the reasons why antipsychotic medication is being administered over the person's objection or lack of consent.

If antipsychotic medications are administered over the patient's lack of consent, and if the patient is on or being petitioned to be placed on a 180-day court order, a petition for an order authorizing the administration of antipsychotic medications must be filed on the next judicial day. The hearing must be held within two judicial days. If deemed necessary by the physician with responsibility for the treatment of the person, administration of antipsychotic medications may continue until the hearing is held.

TREATMENT REFUSAL

62. What should I do about refusal of treatment?

[17] This provision appears specifically in Washington administrative regulations governing the involuntary mental health treatment process. It is unclear, however, how this provision would be interpreted by the courts, and its implications are problematic. If you have a patient situation involving this issue, a risk management consult is recommended.

[18] There are additional options for non-consensual administration of anti-psychotic medications once the initial hearing has taken place if two physicians agree. Contact Risk Management if you have specific questions about this.

A competent adult may refuse treatment for any reason, no matter how unwise the decision may appear to others. Refusal to consent and/or withdrawal of consent by a competent adult must be honored. The refusal should be documented in the medical record, including a description of the risk-benefit discussion with the patient. There are specific forms available for documentation (UH2063 for blood refusal; UH2225 for all other treatment refusals). If possible, the patient (or surrogate, as applicable) should sign the refusal form.

If you have concerns about the patient's capacity for decision-making, you should involve the surrogate decision-maker in the discussion. You also may wish to consult Ethics and/or Risk Management/

See the discussion in 54, above, for refusals involving minors. See the discussion in 45 and 46, above, for refusals and other treatment disputes involving surrogates.

63. What about obstetric patients who refuse interventions (such as Caesarean section)?

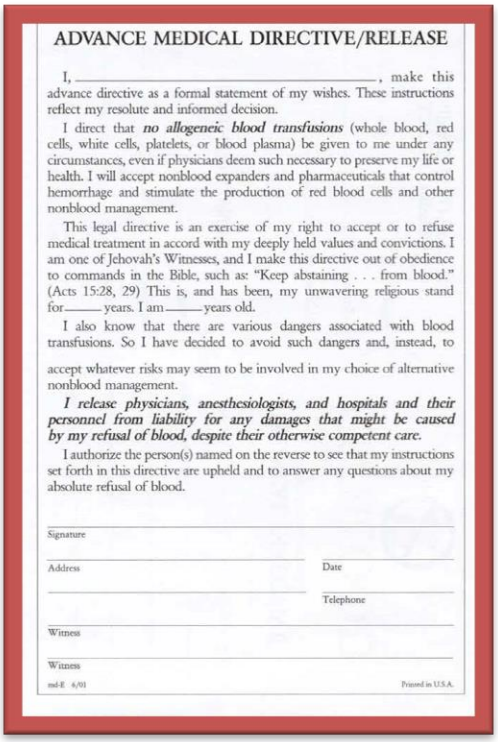
As discussed in 41, above, the mother (if competent) is the decision-maker in these situations, and the fetus does not have legal standing. This means that the mother may refuse intervention even if that refusal seriously endangers her life and/or well-being or that of the unborn fetus. If you have concerns about the mother's competence, you may be able to turn to a surrogate to decide about care for the mother (there is no surrogate for a fetus); however, if the mother is affirmatively refusing care and has questionable capacity, you should consult Risk Management and reevaluate of the mother's capacity.

If the mother has decision-making capacity and is refusing intervention, you should thoroughly document in the medical record, including the risk-benefit discussion and the consequences of refusal you described to the patient. Be very specific in describing the consequences of refusal to the patient, including the "worst case scenario" for both mother and baby. There is a specific form available for refusal documentation (UH2225); try to have the patient sign the form if possible.

64. What about blood refusal?

Consent for blood administration related to a procedure is included in the Special Consent for Procedural Treatment (UH0173). There also is a specific consent form for blood administration not associated with a procedure (UH1148). If the patient wishes to refuse or partially refuse blood administration (e.g., consent only to certain components), they should sign form UH2063.

As with any treatment refusal, a competent adult may refuse blood. If a surrogate wishes to refuse blood on behalf of a patient who is unable to make his/her own decisions—particularly where blood is emergently needed—there should be clear evidence such that you are comfortable that the patient would have refused the blood if competent. An example of this is a Jehovah's Witness card refusing blood (formerly known as a "blood card", it is now called an "advance directive").



ADVANCE MEDICAL DIRECTIVE/RELEASE

I, _____, make this advance directive as a formal statement of my wishes. These instructions reflect my resolute and informed decision.

I direct that ***no allogeneic blood transfusions*** (whole blood, red cells, white cells, platelets, or blood plasma) be given to me under any circumstances, even if physicians deem such necessary to preserve my life or health. I will accept nonblood expanders and pharmaceuticals that control hemorrhage and stimulate the production of red blood cells and other nonblood management.

This legal directive is an exercise of my right to accept or to refuse medical treatment in accord with my deeply held values and convictions. I am one of Jehovah's Witnesses, and I make this directive out of obedience to commands in the Bible, such as: "Keep abstaining . . . from blood." (Acts 15:28, 29) This is, and has been, my unwavering religious stand for ____ years. I am ____ years old.

I also know that there are various dangers associated with blood transfusions. So I have decided to avoid such dangers and, instead, to accept whatever risks may seem to be involved in my choice of alternative nonblood management.

I release physicians, anesthesiologists, and hospitals and their personnel from liability for any damages that might be caused by my refusal of blood, despite their otherwise competent care.

I authorize the person(s) named on the reverse to see that my instructions set forth in this directive are upheld and to answer any questions about my absolute refusal of blood.

Signature

Address

Date

Telephone

Witness

Witness

md-E 6/01

Printed in U.S.A.

See the discussion in 54, above, for refusals involving minors. Please consult Risk Management in these situations.

HMC APOP 85.7--Refusal of Blood Products-Medical and Surgical Options

OTHER "CONSENT" FORMS

65. What is the difference between "informed consent" and the form that patients sign when they are first admitted to the hospital or come to a clinic?

The "Care Agreement" form signed on admission to the hospital or at the first clinic visit does not meet informed consent criteria (for example, it is typically presented to the patient by a staff member who does not have a state law scope of practice covering any part of the informed consent process). The Care Agreement is more contractual in nature and constitutes a basic acknowledgment that the patient has come to the facility seeking treatment. It should be signed by the patient or his/her surrogate before care is rendered or when the patient or surrogate is able to sign.

It is not useful as a basis for proceeding with more than the most routine care (IV placement, low-risk medication administration, etc.). A discussion must take place with the patient/surrogate regarding all treatment beyond that level (unless there is an emergency). A signed consent form must be used when indicated.

66. What is the difference between UW Medicine informed consent and forms that need to be completed for DSHS patients undergoing sterilization or termination of pregnancy procedures?

The DSHS form is in essence a financial form. DSHS requires that the form be completed before it will agree to pay for sterilization or pregnancy termination. Although the DSHS form contains language that is related to informed consent criteria, it should not be used as the UW Medicine informed consent from the patient. UH0173 should be completed as well, either referencing a set of patient education materials or otherwise documenting the specific consent discussion.

67. What is the difference between informed consent for treatment purposes and informed consent for research purposes?

Human subject research requires a completely separate and detailed informed consent process, the details of which are beyond the scope of this manual. Any and all care that is part of a research protocol must be consented to according to both Federal and University research criteria. There are specific requirements for subjects who are formally enrolled in a study as well as for individual "emergency" or "compassionate" use of a research drug or device in a non-enrolled patient. The UW Human Subjects Division is a source for more detailed information, including the SOP Consent Documentation.

If the patient is receiving other, non-research related care at the same time he/she is undergoing research-related care, the informed consent principles, guidelines and procedures in this manual apply.

68. What is the difference between informed consent and consent to share or release protected health information (PHI) about a patient?

Use and disclosure of PHI is governed by a separate set of laws and requirements than informed consent, including federal law (HIPAA), state law (Washington's version of the Uniform Health Care Information Act), and TJC requirements. Authorizations to use/disclose PHI, and the circumstances under which they are required, does not involve "consent" from an informed consent perspective. For more information on this topic, see UW Medicine's Privacy Policies.

69. What is the difference between informed consent and consent for photography/video, etc.?

This is one of the most common areas confused with "informed consent." Photography and other imaging issues are governed by privacy law and policies as noted above. See the UW Medicine Notice of Privacy Practices for information on PHI that is considered part of "treatment, payment or operations" (i.e., no separate authorization required if imaging is used for these purposes), and the Patient Authorization to Use or Disclose Photography/Video for use when indicated.

UW Medicine Privacy Policies only cover images taken by or on behalf of UW Medicine. Photographs and videos taken by patients' families and other visitors should be handled as visitor

behavior issues, with involvement of Patient Relations and Public Safety as appropriate. See UWMC APOP 85-6: Family and Visitor Guidelines; HMC APOP 5-9: Visitor Policy.

70. What is the difference between informed consent and "consent" for organ donation or autopsy?

Organ donation and autopsy permissions are not "informed consent" issues, as they are governed by separate laws. For example, the list of persons who may authorize an autopsy or organ donation is similar, but not the same as the list of surrogate informed consent decision-makers.

HMC APOP Policy Number 80.16: Organ and Tissue Donation
UWMC APOP Policy Number 5-30: Organ and Tissue Donation
UH0430 (contains instructions on obtaining autopsy permission, including information about persons authorized to give permission)

RCW Chapter 68.50

ADDITIONAL RESOURCES

1. Risk Management Contact Information

   Call Health Sciences Risk Management at 206 598-6303, or email at hsrmhelp@uw.edu.

2. Informed Consent Algorithm

3. WSHA: Washington Health Law Manual, Third Edition

4. American College of Surgeons Statement of Principals April 12, 2016

5. UW Medicine Overlapping Surgery Memorandum, Issued 06.23.2017

6. UW Medicine "Core Consent" Forms
   - Special Consent for Procedural Treatment, UH0173
   - Special Consent for Anesthesia/Sedation, UH2227
   - Consent for Transfusion of Blood or Blood Components, UH1148
   - Refusal and/or Partial Consent for Blood/Blood Components, UH2063
   - Special Consent to Medical Care – Treatment or Testing, UH2224
   - Refusal of Treatment, UH2225
   - Emergent Treatment Confirmation, UH2226 (not a consent form)

7. UW Medicine Privacy Policies