AUA
VOLUME 40 UPDATE SERIES LESSON 30
2021

Informed Consent

Learning Objective: At the conclusion of this continuing medical education activity, the participant will be able to describe the components required for adequate informed consent, define standards for informed consent of minor age patients and list important elements for informed consent of human subjects involved in clinical research.

This AUA Update aligns with the American Board of Urology Module on Core/General Urology. Additional information on this topic can be found in the AUA Core Curriculum section on Ethics.

C. Adam Lorentz, MD,[1] Adam C. Webb, MD[2] and Chad W. M. Ritenour, MD[3]

[1]Assistant Professor, Department of Urology, Emory University, Atlanta, Georgia

[2]Associate Professor, Departments of Neurology, Neurosurgery and Pediatrics, Emory University, Chief Quality Officer, Emory University Hospital, Emory Healthcare, Atlanta, Georgia

[3]James C. Kennedy Professor in Prostate Health, Department of Urology, Chief Medical Officer, Emory University Hospital, Emory Healthcare, Atlanta, Georgia

All authors: nothing to disclose.

American Urological Association

Accreditation: The American Urological Association (AUA) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

Credit Designation: The American Urological Association designates this enduring activity for a maximum of 1.0 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Other Learners: The AUA is not accredited to offer credit to participants who are not MDs or DOs. However, the AUA will issue documentation of participation that states that the activity was certified for *AMA PRA Category 1 Credit™*.

Evidence Based Content: It is the policy of the AUA to ensure that the content contained in this CME activity is valid, fair, balanced, scientifically rigorous, and free of commercial bias.

AUA Disclosure Policy: All persons in a position to control the content of an educational activity (i.e., activity planners, presenters, authors) are required to disclose to the provider any relevant financial relationships with any commercial interest. The AUA must determine if the individual's relationships may influence the educational content and resolve any conflicts of interest prior to the commencement of the educational activity. The intent of this disclosure is not to prevent individuals with relevant financial relationships from participating, but rather to provide learners information with which they can make their own judgments.

Disclosures for all individuals in control of content, including the Update Series Editorial Committee, COI Review Work Group, Lesson Authors, and AUA Staff are available in the online lesson located in the AUAUniversity.

Mitigation of Identified Conflict of Interest: All disclosures will be reviewed by the AUA Conflict of Interest (COI) Review Work Group for identification of conflicts of interest. The AUA COI Review Work Group, working with the program directors and/or editors, will document the mechanism(s) for management and mitigation of the conflict of interest and final approval of the activity will be documented prior to implementation. All relevant financial relationships for this lesson have been mitigated. Any of the mechanisms below can/will be used to mitigate conflict of interest:

- Peer review for valid, evidence-based content of all materials associated with an educational activity by the course/program director, editor, and/or AUA COI Review Work Group.
- Limit content to evidence with no recommendations
- Introduction of a debate format with an unbiased moderator (point-counterpoint)
- Inclusion of moderated panel discussion
- Publication of a parallel or rebuttal article for an article that is felt to be biased
- Limit equipment representatives to providing logistics and operation support only in procedural demonstrations
- Divestiture of the relationship by faculty

Off-label or Unapproved Use of Drugs or Devices: The audience is advised that this continuing medical education activity may contain reference(s) to off-label or unapproved uses of drugs or devices. Please consult the prescribing information for full disclosure of approved uses.

Release date: September 2021

Expiration date: September 2024

Key Words: informed consent, disclosure, biomedical ethics, clinical research, urology

WHAT IS INFORMED CONSENT?

In basic principle, informed consent is permission granted by an individual to undergo a medical intervention or participate in a research study after full understanding of the circumstances. This highlights the communication necessary to provide information that ensures such understanding. The process itself might be thought of as a clinical skill, yet there is little standardized education and training on how to adequately obtain informed consent.[1] Many simply recognize the consent process as a required signature on a form before engaging the patient in a surgery or other procedure. However, informed consent is much more than that, and its concept and scope continue to evolve with time.

Informed consent can be considered both a legal and an ethical responsibility. The American Urological Association Code of Ethics states that the urologist must "consider informed consent integral to providing appropriate medical or surgical care."[2] The American College of Surgeons and the American Medical Association both have standards related to informed consent.[3,4] Moreover, failure to obtain adequate informed consent exposes the provider/researcher and parent institution to medicolegal risk, as both federal and state laws require the process.[1] Regardless, the theoretical informed consent process does not often match what is practically done.[5,6]

Informed consent supports the ethical principles of autonomy and beneficence. **Patients have a right to self-determination regarding decisions affecting their health.** This is embodied in the decision of Justice Benjamin Cardozo in the case of *Schloendorff v. Society of New York Hospital* (1914): "Every human being of adult years and sound mind has a right to determine what shall be done with his own body…."[7] In this case, the patient alleged that, while she had provided consent to an examination under ether, she had not given permission for the excision of a tumor discovered. The court's decision demonstrated respect for patient autonomy.

Physicians also have a fiduciary duty to patients for transparency regarding health-related decisions.[8] This is based on both the ethical principle of beneficence and the basic moral principle of truth-telling. The requirement for "full disclosure of facts necessary to an informed consent" is credited to the landmark decision of *Salgo v. Leland Stanford Jr. University Board of Trustees* (1957), which also introduced the term "informed consent".[7] In this case, Mr. Salgo suffered paralysis following translumbar aortography and alleged negligence on the part of his doctors in failing to warn him of this risk. The court found that "a physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment."[7] Successful informed consent practices improve the relationship between patients and physicians by fostering trust.

While there is some recent improvement, including use of technological applications, the process of obtaining and documenting informed consent still lacks standardization across health care settings.[9] Similarly, the specific professional standards used to determine adequacy of informed consent may vary by specialty and setting. In this Update, we incorporate recent information on informed consent in clinical and research arenas that may be encountered by the practicing urologist.

COMPONENTS OF INFORMED CONSENT AND DOCUMENTATION

Despite variation in local laws and institutional policies, several generally accepted components are required for informed consent. These include ensuring that the patient/subject has 1) the capacity to consent, 2) understanding of information presented and 3) the ability to voluntarily consent or refuse the intervention.[5,10,11] An important related concept is the amount of information required for disclosure when obtaining consent (see figure). There are some differences in a clinical setting compared to research, which is also governed by federal regulation as well as institutional review boards that monitor local processes.

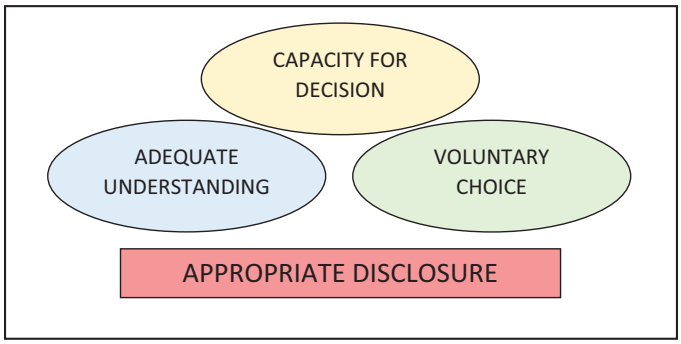

Figure. Basic components of informed consent.

Simple (implicit) consent varies from informed (explicit) consent. Most basic medical procedures, such as blood draws, do not follow the same consent processes as complicated interventions. There is acceptance that patients' participation in the health care process implies simple consent for basic interventions with limited risks.[12] Several instances, like life-threatening situations, may not require informed consent, but even in these cases, an alert patient or their surrogate has the ability to refuse treatment.[8] Rarely, therapeutic privilege may be used to withhold certain information from patients that could be harmful to their well-being.[10]

Documentation of informed consent typically occurs on a standard form in most hospital and ambulatory settings. This form does not ensure that a valid informed consent process was performed, but it is a reproducible piece of medical documentation to support such a process. Handwritten forms have been replaced with templated, including electronic, versions.[6]

ABBREVIATIONS: CFR=Code of Federal Regulations

Irrespective of these forms, physicians should still document the discussion of potential risks, benefits and alternatives in the patient's medical record. This is especially important, since other members of the medical team may actually complete the form with the patient. There recently has been legal precedent in Pennsylvania that treating physicians should be the only ones performing the consent process for their patients.[13]

Capacity and surrogate decision makers. Physicians will encounter patients with compromised decision-making ability. This could be due to a variety of conditions, including cognitive impairment or temporary incapacitation, and affects the capability to provide informed consent. Likewise, many pediatric patients are not able to legally provide consent for themselves. In these cases, surrogate decision makers are critically important.

Several terms, including capacity and competence, are often used interchangeably to describe a patient's ability to participate in medical decisions. **In one common definition, capacity refers to a clinical judgment of the patient's ability to participate in decisions, whereas competence is a legal assessment as to one's ability to manage affairs through global decision-making.[10,14]** However, these are generally related.

Physicians have a duty to assess the capacity of the patient to participate in the informed consent process.[15] This may not be an easy assessment to perform, although there are several validated instruments which might be helpful.[14] These may be time-consuming, particularly in situations where urgent treatment is needed, and are not necessary for all patients. **Capacity can also change over time, as patients clinically improve or decline, requiring continual assessment. Patient capacity assessment for decision-making during the informed consent process is important to document.[15]** A psychiatric evaluation may be necessary for certain patients.[16]

The Patient Self-Determination Act is federal law that requires patients have the ability to participate in medical decisions.[17] It also provides guidance on advance directives, which lay out a patient's preferences in case there are times when he/she is incapacitated and unable to participate directly. These advance directives can allow for surrogate decision makers, or health care powers of attorney, to act as legal proxies on the patient's behalf, if necessary.[15] Understanding who is legally authorized to make decisions for patients should be an important part of the overall care plan.

Understanding and communication. **Satisfactory informed consent depends on adequate understanding of that for which one is actually giving consent.[18]** However, the multiple types of both patients and providers encountered create opportunities for a disconnect between individuals and can compromise the integrity of the consent process. Both patient factors (eg native language, health literacy and situational anxiety) and provider factors (eg communication skills, knowledge of details and cultural competency) can foster different understanding of the information presented between parties. Additionally, the true measurement of patient understanding has been difficult to assess. Several key interventions have been promoted to improve the process.

One common challenge for medical providers is consenting patients with limited English proficiency. Patients with limited English proficiency deserve the same quality process as others but often require more time due to the language barrier. **Law mandates that such patients have access to qualified medical interpreters to satisfy conditions for federal funding.[19] Studies have also shown that medical interpreters improve patient engagement and informed consent.[20]** Despite this, many providers continue to rely on their own limited language proficiency or interpretations from family members or friends of patients, and this has potential patient safety consequences.[19] There are also cultural implications that could influence the trust required for informed consent.[5] For example, there may be implications of a signed paper, as opposed to verbal consent, or deference to older family members to give permission.[21] Attention to the cultural influences of patients, through use of translated materials and attempts to elicit understanding in culturally sensitive ways, is important, as silence does not always mean agreement.

The complexity of current medical interventions is challenging to comprehend, and many individuals lack even basic health literacy. **Use of terminology beyond elementary reading levels is a barrier to understanding for large numbers of patients during the informed consent process.[22] Visual decision aids and other decision-making support tools have been identified as helpful for these patients.[23]** A model that asks individuals to consent to a generally broad concept of what is to be done, rather than the specific technical details, has also been suggested.[5]

Clearly, one method of communication for informed consent will not be effective for all individuals. Perhaps the most important, but challenging, goal is to assess and confirm understanding from the person giving consent, as a means of measuring the success of such communication. The ideal of confirmed understanding may not always overlap with the practical situation, given constraints on providers and the systems in which they work. General strategies, like visual aids and teach-back techniques, which engage the patient, can be effective.[21] For the past 10 years, we have used a short video that reviews the specific consent form (as opposed to technical aspects of the medical procedure) just before basic ambulatory urological procedures as an augment to any prior discussion between patient and provider.

Voluntary consent and refusal. **A hallmark of informed consent is that individuals are voluntarily able to give permission or refusal to proceed with the proposed plan.[5,8]** If the patient or research subject is under duress, then his/her right to self-determination is compromised. Therefore, medical providers must be careful to avoid coercion in the process of obtaining informed consent.[24]

The conditions surrounding the person giving consent or refusal are also important. **If there are effects from medication or stress that could affect clear thinking, then circumstances are not optimal for ethical consent.[8]** Examples would be family members placing undue pressure on a patient to refuse a surgical procedure or to agree to participate in a clinical trial.[11]

DISCLOSURE

Although there is considerable variability in the exact information given to patients, there is legal guidance around basic information required for disclosure during the informed consent process. Regardless, there remain areas without clear legal or local institutional requirement. The extent of disclosure necessary can be challenging as the amount of available medical information increases and health policy continues to change. The Joint Commission requires a written informed consent policy as an accreditation standard for participating hospitals, with a process that involves discussion of at least the following

elements: proposed treatment plan; potential risks, benefits and side effects of proposed plan; likelihood of patient achieving goals; any potential problems that might occur during recuperation; reasonable alternatives, including any potential risks, benefits and side effects; and risks of not receiving the proposed care plan (see table).[25] Professional societies may also set criteria by specialty.

Other components, beyond basic elements, have been debated in relevance to the informed consent process.[26] Provision of information around surgeon-specific experience, including complication and mortality rates, is controversial and thought to be difficult to interpret.[27] Likewise, there are questions around whether medical costs or physician conflicts of interest should enter the consent discussion.

Adequacy of informed consent can be relative to the applied legal standards, which vary by state. Most states utilize either the reasonable physician or the reasonable patient standard for legal challenges regarding the level of information provided. The reasonable physician standard relies on whether the relayed information is what a reasonable physician would provide to a patient and depends on expert testimony by peers. Comparatively, the reasonable patient standard measures what a reasonable patient would expect to know to make an informed decision.[6,8,10,28]

Medical practice has generally moved from paternalistic management, when the physician would always choose what is best for the patient, toward shared decision-making.[10–12] **Shared decision-making is a model where the physician and patient engage in a deliberative process around a decision with multiple clinically acceptable options.** This bolsters informed consent and is particularly effective in situations where there may be relative uncertainty regarding potential benefits and harms. Under these conditions, physicians make patients aware that there is a choice, then describe each option and finally ask questions aimed at eliciting the patient's values and preferences.[29]

In shared decision-making, choices are based around what is valued most. Important goals might include prolonging life, minimizing potential suffering and pain, or limiting disability. There are several examples in urology, including clinically localized prostate cancer, where a shared decision model is effective.[30] For common situations, decision aids or tools may be developed to assist in patient communication and deliberation.[31]

Table. Elements to consider during clinical informed consent discussion

Proposed care treatment plan*
Potential risks, benefits and side effects of proposed plan*
Likelihood of patient achieving goals*
Potential problems that might occur during recuperation*
Reasonable alternatives, including potential risks, benefits and side effects of each*
Risks of not receiving proposed care plan*
Surgeon-specific experience, including complication and mortality rates
Medical costs
Physician conflicts of interest
Specialty-specific recommendations

*Required by Joint Commission accreditation standards.[25]

VERIFICATION OF SURGICAL CONSENT AND ALTERING PLANNED PROCEDURE

The surgical consent process has the potential for human error with serious downstream consequences. If the patient laterality (side) for a procedure is marked incorrectly on a consent form and not identified, a wrong site surgery could potentially occur. Fortunately, the overall occurrence of wrong site errors is rare, but putting standard work in place to ensure all steps are aligned is important.

Universal protocol involves accreditation standards of the Joint Commission and represents a standardized process to prevent errors.[25] Requirements include verification of the patient, procedure and site both in the pre-procedure period and immediately at the time of the procedure. This verification occurs through a formal "time out" discussion with all relevant parties and encompasses review of supporting materials, often including the signed consent form, in the medical record.[32] The "time out" may also be included within a more comprehensive surgical checklist, which could also capture review of the consent form specifically, as a best practice.[33]

Even with outstanding protocols, unexpected findings or events still occur during surgery. Therefore, processes should incorporate considerations for alteration of planned procedures. Discussion of any possible intraoperative scenarios with the patient in the preoperative period allows for plans if any such conditions are encountered. However, there still may be times when a surgeon must make a decision that could significantly change or augment the planned procedure.[34] **In those settings, with the patient temporarily incapacitated and often under anesthesia, the surgeon should make every attempt to discuss findings with patient's surrogate decision maker, or next of kin, to reach the best decision about how to proceed and then document those discussions in the medical record.**

SPECIFIC CONSIDERATIONS AROUND INFORMED CONSENT

Consent for telehealth. The COVID-19 pandemic rapidly accelerated development and use of telehealth. **Like all medical care, telehealth should involve the informed consent process when discussing treatment.** However, telehealth may be best thought of as a method of care delivery rather than a specific procedure itself.

The regulatory landscape for telehealth will likely change as the model becomes more mainstream. Currently, the Centers for Medicare and Medicaid Services do not require written informed consent prior to each provision of telehealth services. However, many state regulations do, so practices should review applicable local statutes, particularly Medicaid guidelines, governing health care delivery.[35] In certain situations, states may allow that consent be granted verbally, with documentation in the medical record for compliance. The Centers for Medicare and Medicaid Services do require annual beneficiary consent for medical care, and telehealth-specific language may be included in this global consent form. Relaxation of certain guidelines during the COVID-19 pandemic has allowed this consent to be granted after delivery of non-face-to-face services.[36] The language for informed consent should explain the nature of telehealth, discuss expectations including limitations, and outline benefits and possible risks such as technical difficulty.[37]

Consent for pediatric patients. **Pediatric patients have the same ethical right of autonomy related to their bodies.**

However, until they reach the legal age of consent, parents or guardians maintain the ability to authorize treatments for minor patients in most cases. Young patients should still have the opportunity to participate in their care, as children longitudinally gain skills to participate in decision-making as they developmentally mature, unlike adults.[27] Whenever children are able to comprehend diagnosis and treatments, they should be given age-appropriate information about their care plans. The data specifically around surgical informed consent in pediatrics are limited.[24]

Because most patients less than 18 years old cannot legally give permission for medical treatment, the concept of assent has been promoted. **Assent is meant to capture the patient in the consent process and includes at least the following, according to the American Academy of Pediatrics: assisting patient to reach developmentally appropriate awareness of condition, providing expectations regarding tests or treatments, performing clinical assessment of patient's understanding of situation and factors influencing response to it, and soliciting a willingness to accept proposed care.**[27] Others have promoted more of a formal consent process for older children, with a dual consent for both patient and parent or guardian.[38]

Adolescent patients especially should be part of the decision-making process. Physicians often provide and ensure confidentiality to these young patients for sensitive medical conditions, in order to promote their seeking care when necessary.[27,39] This includes care related to sexual activity, such as treatment for sexually transmitted infections or provision of contraception materials.[27] Nonetheless, some state laws and insurance billing practices still allow for this information to reach parents or guardians.[39]

In certain situations, minor patients are given the ability to independently provide consent for medical decisions. **State laws may vary, but individuals who are recognized as mature minors or emancipated minors are given rights similar to adults.** Mature minors are judicially determined to have reached the level of maturity to make legally binding decisions. Emancipated minors can achieve a status of independence through marriage, active military service or residency away from parents with financial self-support.[27] Additionally, adolescent parents, who have not reached age of legal consent themselves, typically retain the ability to provide consent for their own children.[39]

Consent in transgender medicine. Over the past decades, transgender medicine has rapidly grown, as have the professional, ethical and societal opinions attached to it. Informed consent has been a major concern when adjusting a patient's biological sex through medical and/or surgical intervention. In urology, patients with disorders of sexual development have long provided exposure to similar issues. Over time, there have been philosophical changes regarding the rights of a patient born with ambiguous genitalia, and the responsibilities of the parents and physician in those cases.[40] Traditionally, physicians recommended the best approach for management, usually involving gender assignment based on the appearance of the external genitalia, with the thought that the child could be reared with the assigned sex if this was done early in life. As more has been learned about gender identification, there has been concern that parental consent was not truly "informed" by taking into account potential ultimate effects on the patient, especially with irreversible surgical procedures.[40]

Transgender adults are increasing in numbers, with many clinical practices now encountering these individuals needing medical care. As the view of discordance between identified gender and physical body has gradually moved from a pathological condition to more of a normal variation, medical professionals must still face their own feelings regarding ethical issues like informed consent. For practices assisting patients with medical or surgical gender transition, balancing the ethical principles of respect for autonomy with non-maleficence can be challenging.

Because gender dysphoria can present at all stages of life, age of the patient can influence the understanding of risks involved. Limited previous experiences with cross-gender life, inability to appreciate consequences of requested services and socioeconomic status of patient may also affect reaching a fully informed consent.[41] **Consent for gender transition may be best done over an extended period of time because of the multiple perspectives that must be considered, but this must be balanced with the patient's ability to make his/her own decisions.**[41] In this setting, providers' actions may show lack of insight into their own understanding and practice of the informed consent process by unknowingly inserting their own biases, and this is complicated by the relative lack of long-term data to discuss with patients.[42]

CLINICAL TRIALS AND HUMAN SUBJECTS RESEARCH

Advancement of science and medicine is dependent on discovery through research, including clinical trials involving the use of human subjects. **A number of legal protections, such as those for informed consent, exist to ensure ethical conduct of studies.** Many of these protections arose after historical examples of unethical treatment of subjects in previous trials, like those during World War II or the Tuskegee study.[43]

Specifically, title 45 of the Code of Federal Regulations (45 CFR §46) for the U.S. government discusses the protection of human research subjects by the U.S. Department of Health and Human Services, although multiple other federal agencies have adopted the same language in their respective sections of the CFR.[44] Subpart A of 45 CFR §46 is known as the "Federal Policy for the Protection of Human Subjects," or frequently as the "Common Rule." **Any human subject research supported by the federal government is subject to the Common Rule requirements, although each agency retains final authority to determine whether a particular activity falls into that category.**[45] In 2017, the Common Rule was revised for the first time to update important understandings in the modern research environment, and these changes took full effect in January 2019.[46]

The Common Rule changes affect the informed consent process.[43,47] **One new addition, meant to improve basic understanding of a study by the research participant, mandates use of a summary key information section as part of the consent form.**[48] **Another change involves a requirement to discuss what will happen to any biospecimens collected as part of a research study and specifically if they will be used in additional studies, even if stripped of individual identifiers.**[43,48] Additionally, the Common Rule requires an actual copy of the consent form be posted to a federal website, with www.ClinicalTrials.gov as the most common repository of this information.[49] For reference, the required basic elements for informed consent under the Common Rule are listed in the Appendix.

As technology changes, unique research also evolves with time. New studies can challenge conventional views of a face-to-face conversation and physical signatures on consent

forms. Internet-based clinical trials are becoming increasingly common and can recruit subjects without physically being in their presence.[9] The advent of wearable devices and smartphones has created the ability to collect ongoing data from research subjects, and app-based trials can pose some challenges for informed consent, particularly as subjects may be unknowingly exposed to data security issues.[9]

With the expanding understanding of both health and disease, combined with ability to do genetic sequencing, there may be data generated during a study that eventually yield important information unknown at the time. Likewise, there sometimes may be opportunity to do new analysis on collected research subjects' tissue or specimens. Because consent may not be possible for the full specifics of future research, some have discussed whether it is ethically reasonable to consent for an oversight mechanism that provides guidance rather than consent for specific details (consent to be governed).[5]

The balance of true informed consent and changing research will continue to create ethical questions. The demand for new diagnostics and treatments has perhaps never been pushed as fast as during the current COVID-19 pandemic. Researchers have been faced with both the desire to do good science with data-driven analysis and the public demand for fast implementation. In these cases, data from ongoing clinical treatment of patients are also being used for active research in a hybridized fashion that can create some challenges for priorities in the individuals involved. As one discusses clinical trials and research studies with patients, especially ones who are acutely ill, and their surrogates, he/she must still pay attention to the basic principles of informed consent as best as possible.

CONCLUSIONS

Informed consent is an opportunity for the urology provider to participate in patient-centered care and is more about the process than any signature on a form. The components of capacity, adequate understanding and voluntariness are central to informed consent, which may occur over more than just one visit. The amount of information disclosed to individuals during the consent process is subject to regulatory standards, but this should also reflect what is truly needed to inform the person giving permission. Societal changes will continue to add new questions that challenge the goal of ideal informed consent.

This Update is meant to supplement a previous version (Volume 31, Lesson 26, 2012) on the same topic with a review of key points and addition of relevant recent information since that time.

DID YOU KNOW?

- Valid informed consent requires that the individual have the capacity to consent, adequate understanding of the situation and ability to voluntarily give permission or refusal.
- Pediatric patients should be involved in the informed consent process as age-appropriate and provide assent if possible, even if they cannot legally give permission without parent or guardian.
- Informed consent for research studies involving human subjects in the U.S. has required elements as defined by the Common Rule in the Code of Federal Regulations (45 CFR §46).

Appendix. Required basic elements of informed consent for human subjects involved in research from U.S. Department of Health and Human Services Office of Human Protections [44,48]

A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental.

A description of any reasonably foreseeable risks or discomforts to the subject.

A description of any benefits to the subject or to others that may reasonably be expected from the research.

A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens.

- A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
- A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

REFERENCES

1. Bagnall NM, Pucher PH, Johnston MJ et al: Informing the process of consent for surgery: identification of key constructs and quality factors. J Surg Res 2017; **209:** 86.
2. American Urological Association: Code of Ethics. Available at https://www.auanet.org//myaua/aua-ethics/code-of-ethics. Accessed October 22, 2020.
3. American College of Surgeons: Statements on Principles. Available at https://www.facs.org/about-acs/statements/stonprin#iia. Accessed October 22, 2020.
4. American Medical Association: Code of Medical Ethics: Consent, Communication & Decision Making. Available at https://www.ama-assn.org/delivering-care/ethics/code-medical-ethics-consent-communication-decision-making. Accessed October 22, 2020.
5. Grady C: Enduring and emerging challenges of informed consent. N Engl J Med 2015; **372:** 855.
6. Leclerq WKG, Keulers BJ, Scheltinga MRM et al: A review of surgical informed consent: past, present, and future. A quest to help patients make better decisions. World J Surg 2010; **34:** 1406.
7. Wandler M: The History of the Informed Consent Requirement in United States Federal Policy (2001 third year paper). Available at http://nrs.harvard.edu/urn-3:HUL.InstRepos:8852197. Accessed October 25, 2020.
8. Paterick TJ, Carson GV, Allen MC et al: Medical informed consent: general considerations for physicians. Mayo Clin Proc 2008; **83:** 313.
9. Grady C, Cummings SR, Rowbotham MC et al: Informed consent. N Engl J Med 2017; **376:** 856.
10. Cocanour C: Informed consent—it's more than a signature on a piece of paper. Am J Surg 2017; **214:** 993.
11. Jones B: Legal aspects of consent. BJU Int 2000; **86:** 275.
12. Whitney SN, McGuire AL and McCullough LB: A typology of shared decision making, informed consent, and simple consent. Ann Intern Med 2004; **140:** 54.
13. Fernandez Lynch H, Joffe S and Feldman EA: Informed consent and the role of the treating physician. N Engl J Med 2018; **378:** 2433.
14. Sturman ED: The capacity to consent to treatment and research: a review of standardized assessment tools. Clin Psychol Rev 2005; **25:** 954.
15. Fields LM and Calvert JD: Informed consent procedures with cognitively-impaired patients: a review of ethics and best practices. Psychiatry Clinical Neurosci 2015; **69:** 462.
16. Shah P, Thornton I, Turrin D et al: Informed consent. In: StatPearls. Treasure Island, Florida: StatPearls Publishing 2021. Available at https://www.ncbi.nlm.nih.gov/books/NBK430827/. Accessed October 25, 2020.

17. Thobaben M and Proctor C: Patient self-determination act: advocating for the patient's wishes. Home Care Provid 1996; **1:** 157.
18. Pugliese OT, Solari JL and Ferreres AR: The extent of surgical patients' understanding. World J Surg 2014; **38:** 1605.
19. Patel DN, Wakeam E, Genoff M et al: Preoperative consent for patients with limited English proficiency. J Surg Res 2016; **200:** 514.
20. Lee JS, Pérez-Stable E, Gregorich SE et al: Increased access to professional interpreters in the hospital improves informed consent for patients with limited English proficiency. J Gen Intern Med 2017; **32:** 863.
21. Joint Commission: Informed consent: more than getting a signature. Quick Safety, February 2016, issue 21.
22. Tamariz L, Palacio A, Robert M et al: Improving the informed consent process of research subjects with low literacy: a systematic review. J Gen Intern Med 2012; **28:** 121.
23. Elwyn G, Scholl I, Tietbohl C et al: "Many miles to go…": a systematic review of the implementation of patient decision support interventions into routine clinical practice. BMC Med Inform Decis Mak, suppl., 2013; **13:** S14.
24. Chotai PN, Nollan R, Huang EY et al: Surgical informed consent in children: a systematic review. J Surg Res 2017; **213:** 191.
25. Joint Commission: E-dition. September 13, 2020. Available at https://edition.jcrinc.com/MainContent.aspx. Accessed October 28, 2020.
26. Givel J-C and Meier B: How much information do patients want or need. World J Surg 2014; **38:** 1610.
27. Katz AL, Webb SA and American Academy of Pediatrics Committee on Bioethics. Informed consent in decision-making in pediatric practice. Pediatrics 2016; **138:** e20161485.
28. Wheeler R: The evolution of informed consent. Brit J Surg 2017; **104:** 1119.
29. Elwyn G, Frosch D, Thomson R et al: Shared decision making: a model for clinical practice. J Gen Intern Med 2012; **27:** 1361.
30. Sanda MG, Cadeddu JA, Kirkby E et al: Clinically localized prostate cancer: AUA/ASTRO/SUO Guideline. Part I: Risk stratification, shared decision making, and care options. J Urol 2018; **199:** 683.
31. Zhong W, Smith B, Haghighi K et al: Systematic review of decision aids for the management of men with localized prostate cancer. Urology 2018; **114:** 1.
32. Papadakis M, Meiwandi A and Grzybowski A: The WHO safer surgery checklist time out procedure revisited: strategies to optimize compliance and safety. Int J Surg 2019; **69:** 19.
33. Yates LA: Clarifying Informed Consent. American Society for Healthcare Risk Management. Available at https://forum.ashrm.org/2019/02/27/clarifying-informed-consent/. Accessed October 27, 2020.
34. Kwek LK, Wee-Stekly W-W and Chern SMB: Uterine fibroid or ovarian fibroma: importance of comprehensive preoperative consent-taking to include unexpected findings with management implications. BMJ Case Rep 2018; 2018: bcr2017222608.
35. Center for Connected Health Policy: Informed Consent. Available at https://www.cchpca.org/telehealth-policy/informed-consent. Accessed October 16, 2020.
36. Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19. Available at https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.pdf. Accessed October 16, 2020.
37. American Medical Association: Ethical Practice in Telemedicine. Available at https://www.ama-assn.org/delivering-care/ethics/ethical-practice-telemedicine. Accessed October 16, 2020.
38. Hein IM, De Vries MC, Troost PW et al: Informed consent instead of assent is appropriate in children from the age of twelve: policy implications to new findings on children's competence to consent to clinical research. BMC Med Ethics 2015; **16:** 76.
39. Maslyanskaya S and Alderman EM: Confidentiality and consent in the care of the adolescent patient. Pediatr Rev 2019; **40:** 508.
40. Reis E: Did bioethics matter? A history of autonomy, consent, and intersex genital surgery. Med Law Rev 2019; **27:** 658.
41. Levine SB: Informed consent for transgendered patients. J Sex Marital Ther 2019; **45:** 218.
42. Shuster SM: Performing informed consent in transgender medicine. Soc Sci Med 2019; **226:** 190.
43. Gartel G, Scuderi H and Servay C: Implementation of common rule changes to the informed consent form: a research staff and institutional review board collaboration. Ochsner J 2020; **20:** 76.
44. Office of the Federal Registrar: Electronic Code of Federal Regulations. Available at https://www.ecfr.gov. Accessed October 22, 2020.
45. Office for Human Research Protections: Federal Policy for the Protection of Human Subjects ('Common Rule'). Available at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html. Accessed October 30, 2020.
46. Office for Human Research Protections: Revised Common Rule. Available at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html. Accessed October 25, 2020.
47. Office for Human Research Protections: Informed Consent FAQs. Available at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html. Accessed October 31, 2020.
48. U.S. Department of Health and Human Services: Companion Q&As about the Revised Common Rule. Available at https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html. Accessed October 31, 2020.
49. Office for Human Research Protections: Clinical Trial Informed Consent Form Posting (45 CFR 46.116(h)). Available at https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/index.html. Accessed October 31, 2020.

Study Questions Volume 40 Lesson 30

1. A 79-year-old man with dementia is undergoing outpatient ureteroscopy with laser lithotripsy. He is found to have a large papillary tumor in the bladder on cystoscopy. The next step is
   a. discuss the findings with his daughter present in the waiting room and ask her to grant consent for resection of the tumor
   b. telephone his health care power of attorney for consent to resect the tumor
   c. complete the ureteroscopy and discuss the findings with his family after surgery
   d. abort the procedure to discuss findings with his family and health care power of attorney prior to proceeding

2. A 45-year-old intubated and sedated patient in the intensive care unit is found to have an obstructing ureteral stone with sepsis. The patient's family is unable to be reached. The next step for the urologist is to
   a. call the patient's friend, listed as an emergency contact, to grant consent
   b. consult the hospital administrator on call for permission to treat
   c. wait until the patient's spouse can be contacted to give consent
   d. proceed with intervention emergently

3. A 19-year-old patient, born as a genetic male, identifies as a female and wishes to undergo medical and surgical transition. The patient has started the formal evaluation process but has not yet had any treatment. Before starting hormonal therapy, the physician should
   a. identify the patient's reasons for wanting therapy, and plan additional visits to continue discussing potential risks and benefits
   b. refuse treatment until the patient has had a psychiatric evaluation
   c. insist the patient join a support group for transgender patients
   d. require the patient to dress as a female for 6 months

4. A 15-year-old boy has a large varicocele identified by his pediatrician. Following a history and physical, when reviewing varicocele repair the urologist should
   a. tell the patient that his verbal assent is all that is needed to proceed with surgery
   b. discuss the potential risks, benefits and alternatives with both patient and mother
   c. have the patient sign a consent form to proceed after he has a chance to ask questions
   d. ask the patient to leave the room prior to discussion with his mother about specifics of the procedure

5. A requirement for informed consent of subjects of human research under the Common Rule is a/an
   a. explanation of the global costs to perform the research
   b. medical description of the study for the patient's primary physician
   c. statement regarding future use of any biospecimens collected as part of the study
   d. confidentiality form that prohibits the subject from telling anyone that he/she is part of a clinical research study