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ACR PRACTICE PARAMETER ON INFORMED CONSENT – RADIATION ONCOLOGY

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiation oncology care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner in light of all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of this document is to assist practitioners in achieving this objective.

¹ *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing*, ___ N.W.2d ___ (Iowa 2013) Iowa Supreme Court refuses to find that the *ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, *Stanley v. McCarver*, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

The process of informed consent is designed to protect a patient's medical decision-making in the context of an asymmetrical relationship with the health care system. A proper consent process assures a patient's individual autonomy, reduces the opportunity for abusive conduct or conflicts of interest, and raises trust levels among participants.

Consent is a communications process between the patient and a health care provider in which both parties have the opportunity to ask questions and exchange information relevant to the patient's diagnosis and treatment. For this process to be effective, both parties must actively participate in the process, and both parties share the responsibility for the accurate exchange of information. Patients have a right to self-determination and to consent to any medical treatment before it is given. Physicians have a legal and ethical duty to obtain informed consent from the patient. The patient and, when required, the patient's family or personal representative, must have every opportunity to understand any treatment or procedure the patient is to receive, to have all questions answered, and to fully consent to treatments and procedures [2-4].

The physician has the duty to help the patient make choices from among the therapeutic alternatives that are consistent with good medical practice. The process should also reasonably guarantee freedom from coercion. Thus the consent must be obtained in a manner that is free from fear of the practitioner's subsequent actions, honors both ethical and legal principles, and minimizes the question of undue inducement. The American Medical Association Code of Medical Ethics outlines its perspective on informed consent in Opinion 8.08 [1]. If medical treatment is given without informed consent being obtained, a claim of battery or malpractice may be made against the physician or health care professional who performs the procedure [2-3,5-6]. For information on exceptions to the informed consent rule, see section II.

Informed consent is a process and not the simple act of signing a formal document. However, the informed consent document provides important documentation of the complex shared decision-making with the patient, and by his or her signature, a patient indicates that he or she understands and consents to the treatments and procedures that will be performed. Informed consent with appropriate documentation must follow institutional policies and procedures and comply with applicable state and federal law.

II. SITUATIONS REQUIRING CONSENT

Informed Consent Rule: Informed consent must be obtained and should be appropriately documented prior to the initiation of any complex medical treatment, including, but not limited to, the following procedures:

1. Imaging for simulation, treatment set-up including field placement, and/or treatment planning; tattoo placement
2. Radiotherapy treatment such as external beam irradiation, radiopharmaceutical therapy, brachytherapy, etc
3. Administration of conscious sedation

Exceptions to this informed consent rule include:

1. Emergency treatment where the patient is unable to provide consent, the patient's legal representative is unavailable, no significant evidence exists to indicate that the patient (or the patient's legal representative) would refuse the treatment, and immediate treatment is required to alleviate a condition causing severe pain or to prevent serious disability or death. In these cases treatment can be given without informed consent. Only the emergency condition may be treated, and if the patient regains ability to consent, or a legal representative becomes available, consent must be obtained for the treatment to continue [2,3].
2. In cases where a patient specifically asks not to be informed of certain facts of their diagnosis or risks of treatment, treatment may be given with less than full disclosure. The request of the patient must be

documented as well as what was discussed and what was omitted. If the patient gives permission for their next of kin or legal representative to receive information relevant to informed consent, the nature of the information given should be documented. At a minimum a patient must be informed:

- a. That the procedure involves some known risks, which may be serious
 - b. That there are some benefits that should be outlined
 - c. That following the treatment there may be some late effects
 - d. About how to cooperate with treatment [3]
3. Therapeutic privilege: Generally, informed consent involves a dialogue between a medical practitioner and a patient. However, in limited situations the practitioner may withhold information from the patient when the disclosure of information to the patient is likely to cause an adverse, potentially substantial impact on the patient or his or her health. Therapeutic privilege may be further defined by case law or legislative enactment. It is a privilege pertinent to the physician based on all the information available and cannot be used to justify withholding information from the patient that the physician knows or should know may cause the patient to refuse treatment because of the risks involved. The quantity and specificity of this information should be tailored to meet the preferences and needs of individual patients [7].

Any significant change in the patient's condition or in the recommended treatment should prompt a re-evaluation of informed consent between the patient and physician. If a patient who was unable to give informed consent becomes able, informed consent must be obtained. The consent should be timely and in accordance with applicable state and federal regulations and facility policies. If there is a significant change in the patient's clinical course between the time when consent is obtained and treatment is performed, then repeating the consent process should be strongly considered [2,3].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

Informed consent for radiation oncology procedures must be obtained by or under the supervision of a licensed physician qualified to perform the procedure. The supervising physician must be familiar with the procedure being performed.

B. Other Health Care Professionals

Other health care professionals may provide information and standardized information materials. Members of the treatment team may also serve to verify that the patient understands the procedure. Ultimately the physician performing the procedure is responsible for the accuracy of the information and for making certain that it is understood by the patient and/or his or her representative [2,3,8,9].

C. Witnesses

It is recommended, but not required (unless by state law), that a witness be present when the patient signs the consent form. All witnesses must be at least 18 years of age or of legal majority in the state where the consent is given. Failure to have the patient's consent witnessed does not invalidate the consent. In cases where a mark is made by a patient to document informed consent, because he or she is unable to provide a signature, the mark must be witnessed. The witness signature serves to verify that the patient signed the consent form.

D. Interpreters

Patients who do not feel competent to understand the language spoken by the physician should be provided with an interpreter who can accurately convey what the physician is saying and can interpret any questions or concerns that the patient may have.

Patients with hearing, vision, speaking, or other communication impairments should be provided with reasonable assistance when necessary to afford such persons the ability to give informed consent.

Although not ideal, if allowed by the institution, patients may, after being informed of the availability of an interpreter, choose to use a family member or friend instead, and if so, their preference should be documented. The use of minors should be avoided.

When interpreters are used, documentation should be placed in the patient's medical record indicating the name of the person who acted as the interpreter and that person's title or his or her relationship to the patient.

E. Patient's Legal Representative

Patients who are unable to consent for themselves, such as minors or incompetent adults, and those who choose to have another person consent for them, have the right to be represented by someone who will protect their interests and preserve their basic rights. State law also may designate who may act for a patient when he or she is incapable of giving consent. In such situations the physician or other qualified person performing the procedure must obtain informed consent from the patient's representative, and arrange for the legal representative's signature on a consent form [3]. In certain rare situations, there may be no identified surrogate decision maker. In such cases, state law and institutional policy should guide the process of consent and, to the best extent possible, follow any wishes which the patient may have previously made known.

IV. SPECIFICATIONS FOR OBTAINING INFORMED CONSENT

A. Standard Procedure

The process to obtain informed consent is designed to facilitate the disclosure of all relevant information according to the individual needs of the patient. This can be tailored to one of several possible standards: the *professional standard*, the level of detail that is conventional for a professional in the field to mention; the *reasonable person standard*, a level that a typical person may desire; or an *individual standard*, a level of detail that the participant determines is appropriate for them. The appropriate standard to apply is primarily dependent upon the patient requirements.

To obtain informed consent, the physician informs the patient or legal representative of:

1. The nature of the patient's diagnosis, what is known of the extent of the disease, the goals of care, and intent of treatment (curative or palliative intent)
2. The nature of the proposed treatment, the parts of the body to be treated (including laterality where relevant), and how the treatment will be given
3. The expected side effects and/or complications that a prudent practitioner would find meaningful [10], including:
 - a. Complications or side effects that occur commonly and are likely to occur
 - b. Complications or side effects that may be rare but are serious if they do occur and that occur with enough frequency that a reasonable patient would want to know about them before deciding to accept treatment. If there is doubt about the likelihood of a complication, that doubt may be communicated as appropriate.
4. Reasonable treatment alternatives
5. The potential benefits of treatment
6. The potential consequences of refusal of treatment [3]

And as relevant:

7. For patients who retain radioactive sources or receive therapeutic radionuclides, the potential risks to family members or to the general public and restrictions for patient and public safety as applicable and/or required by federal, state, or institutional policy
8. The teratogenic effects of radiation therapy for individuals who are of childbearing potential
9. The potential impact of prior radiation therapy on the treatment options and the potential of early- and late-occurring side effects or complications of this treatment course
10. The potential impact of radiotherapy on electronic medical devices such as pacemakers, defibrillators, etc, that may require special monitoring

These must be explained in a way that the patient or legal representative can understand. It is generally recognized that no one method is appropriate for all physicians and all patients [4,8,11-13]. The general underlying principle is that the communication should be sincere and focused on the patient, taking into account cultural and language barriers and individualized to the type of treatment offered [2-4,8,9,12].

It is recommended to include in the patient's medical record reference to any written or other educational materials provided [2,4].

The process of informed consent can take place at the time of consultation or over a period of time including 1 or more follow-up appointments. Informed consent is an iterative process that continues throughout a course of treatment, with provision of new relevant information should any become available. Patients have the right to ask further questions and always retain the right to withdraw consent at any time.

The consent must not be obtained in any coercive way, and the consent form must not contain any coercive statements [2,3].

B. Special Circumstances

1. Underage or incompetent patients
For patients younger than 18 years of age, minors as determined by state law, or incompetent adults, the patient's parent, legal guardian, or person with a medical power of attorney must give informed consent and sign the form [2,3]. In certain rare situations, there may be no identified surrogate decision maker. In such cases, state law and institutional policy should guide the process of consent and, to the best extent possible, follow any wishes that the patient may have previously made known.
2. Consent by telephone or facsimile
When a patient's lawfully authorized representative is available to give informed consent but is not physically present to sign the form, consent by telephone or facsimile may be obtained. The responsible physician must, to the extent possible, provide the patient's legal representative with the information the physician would disclose in a face-to-face discussion. Documentation should include the following information:
 - a. Name and position of person who spoke to the patient's relative or legal representative
 - b. Name and relationship of the legal representative
 - c. A summary of the information conveyed to that representative
 - d. A brief account of questions posed to the representative along with a summary of the answers to these questions
 - e. Date and time of entry in the patient record as well as the writer's signature [3]
 - f. Date, time, and telephone number called
3. Clinical research
If a patient is participating in a clinical research study, he or she must not only give the standard facility informed consent but also sign a study-specific informed consent document. The research study and the consent form must be approved by whatever Institutional Review Board (IRB) has jurisdiction over research at the treating facility prior to initiation of research treatment. If the treating physician is uncertain whether any study involving patients constitutes research requiring IRB approval, that

information can be obtained by contacting the Office of Human Subjects Research in the Office of the Deputy Director for Intramural Research, National Institutes of Health.

V. DOCUMENTATION

A. The informed consent document should contain at least the following:

1. The patient's name and identification number, date of birth, or other second identifier
2. The name of the person(s) or practice group performing the procedure
3. A statement in the first person with the patient's name or the word "myself" authorizing administration of the proposed treatment
4. A statement in the first person that the nature of the treatment, the alternatives, side effects, and risks of injury despite precautions have been explained to the patient or person signing the form for the patient
5. A statement in the first person authorizing tattoos if applicable
6. A statement in the first person authorizing photographs for documentation
7. A statement, when applicable, regarding the risks of radiation related to pregnancy

B. The informed consent document should have a place for:

1. The signature of the patient or patient's representative
2. Relationship of signer if other than the patient
3. The date
4. Reason patient did not sign, if applicable
5. Signature of witness, if applicable
6. Identification of translator, if applicable

C. Additional Information

There must be a place in the permanent medical record, often on a separate page or in the progress notes, where the informing physician:

1. States that he or she has informed the patient of the nature of the procedure or treatment; the risks, complications, and expected benefits or effects of such treatment or refusal; and the alternatives and their risks and benefits
2. States that the patient and/or patient's family have had the opportunity to have their questions answered to their satisfaction
3. Specifies the type of radiation therapy recommended (eg, external beam versus brachytherapy). The type of brachytherapy procedure should be specified, if applicable.
4. Documents the need for immediate treatment for patients treated on an emergency basis. Documentation should include information establishing the nature, immediacy, and magnitude of the problem and the difficulty of obtaining consent under the circumstances. All notes should include the date and time [2,3].
5. Provides special documentation for the rare situations when the patient specifically asks not to be fully informed, or where therapeutic privilege is invoked (see also section II). Communication to specified next of kin or legal representatives of the information withheld from the patient should be documented in the medical record to the extent legally allowed [2,3].

Some states require that special forms be used in the informed consent process in certain circumstances. The informed consent process must comply with state and federal law and with institutional policies and procedures.

A copy of all pertinent consent documentation should be kept in the patient's medical record.

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