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ACR PRACTICE GUIDELINE ON INFORMED CONSENT – RADIATION ONCOLOGY

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines 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 physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, 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 the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations on available resources or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines 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. It should

be recognized, therefore, that adherence to these guidelines 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 these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

Patients have a right to self-determination and to consent to any medical treatment before it is given. Prudent and ethical medical practice requires close communication between the patient and the physician. Physicians have a legal and ethical duty to obtain informed consent from the patient. The patient and, when appropriate, the family 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.

The degree of disclosure required for a valid consent varies from state to state, but there are two generally recognized legal standards. The first is measured by what a reasonable physician in his/her professional judgment believes to be appropriate to disclose to the patient. The degree of disclosure depends on perceptions of the physician in each case. The second legal standard is based on what a reasonable person in the patient's position would want to know under the same or similar circumstances. This reasonable patient standard usually requires greater and more detailed disclosure of information.

If medical treatment is given without informed consent being obtained, a claim of battery may be made against the physician or health care professional who performs the procedure.

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 process of the physician's discussion with the patient, and by his/her signature, a patient indicates that he/she understands and consents to the treatments and procedures that will be performed. Informed consent with appropriate documentation shall follow institutional policies and procedures and comply with applicable state and federal law.

II. SITUATIONS REQUIRING CONSENT

Informed consent shall 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. External beam irradiation, including any tattoos given or photographs taken.¹
2. Brachytherapy procedures.
3. Administration of conscious sedation.
4. Any experimental therapy (this also requires Institutional Review Board (IRB) approval).

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 comes back for a second course of treatment that was not a part of the treatment discussed at the time the original informed consent was obtained, the process should be repeated and informed consent again obtained and a new form signed.

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 Healthcare Professionals

Other healthcare professionals may provide information and standardized information materials. Members of the treatment team may also serve to verify the patient's

understanding of 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.

C. Witnesses

It is recommended that a witness be present when the patient signs the consent form. The witness should observe the patient signing the consent form and then affix his/her own signature to the form in a designated space. All witnesses must be at least 18 years of age or of legal majority in the state where the consent is being given. Failure to have the patient's consent witnessed does not invalidate the consent or create any additional liability.

D. Interpreters

Patients whose primary language is different from that of the physician should have an interpreter who is fluent in a language they can understand. It is recommended that the facility have a policy for interpreter services that complies with applicable federal and state laws and hospital policies.

Federal law requires hospitals (among other entities) that receive or benefit from federal financial assistance to provide interpreters and other aids for persons with impaired hearing, vision, speaking, or other skills when necessary to afford such persons an equal opportunity to benefit from the hospital's services.

A patient may, after being informed of the availability of an interpreter, choose to use a family member or friend instead.

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 position or, when appropriate, his or her relationship to the patient (5).

E. Patient's Legal Representative

Patients who are unable to consent by 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. The physician or other qualified person performing the procedure should talk with the patient and his/her representative, explain the procedure, answer all questions, and arrange for the legal representative's signature on a consent form.

¹For research, presentation, or publication, additional consent should be obtained.

IV. SPECIFICATIONS FOR OBTAINING INFORMED CONSENT

A. Standard Procedure

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

1. The nature of the patient's diagnosis and of the intended treatment.
2. Reasonable treatment alternatives.
3. Potential side effects, common complications, and benefits of treatment.
4. The potential consequences of refusal of treatment.

These must be explained in a way that the patient or legal representative can understand.

The patient and, when appropriate, the family or legal representative must be given every opportunity to understand the treatment or procedure that the patient is to receive and have all questions answered.

The process of informed consent can take place at the time of consultation or over a period of time including one or more follow-up appointments.

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

In some circumstances the patient may elect not to be fully informed. In that situation the consent form or medical record should indicate that the patient would like to proceed with the procedure without further information.

B. Special Circumstances

1. Underage or incompetent patients
All references to the patient refer to a competent adult. 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. 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 if the person were present. When

a telephonic consent between the physician and the patient's lawfully authorized representative is obtained, at least one medical center employee must witness the consent and sign the applicable document(s). The procedures used must meet applicable state and hospital regulations.

3. Emergency treatment

In the case of a medical emergency, treatment may proceed without the patient's consent as long as no evidence exists to indicate that the patient (or the patient's legal representative) would refuse the treatment, such as a particular religious belief or a relative's statement regarding the patient's wishes. In general, a medical emergency exists when immediate diagnosis and treatment of unforeseen medical conditions are required if such medical conditions would lead to serious disability or death.

Only the emergency condition may be treated. Treatment that exceeds that needed for the emergency condition may not be rendered without patient consent.

If a patient or the patient's legal representative has validly exercised his or her right to refuse a particular medical treatment, the treatment may not be provided, even if an emergency arose as a consequence of refusal. If the medical emergency is the result of a condition or injury that is not specifically related to the condition or injury for which the patient previously refused treatment, the emergency treatment exception generally applies.

The need for immediate treatment is documented in the patient's medical record. Documentation includes all information establishing the nature, immediacy, and magnitude of the problem, and the difficulty of obtaining consent under the circumstances. Any consulting physicians should enter their findings and recommendations in the record. All notes should show the date and time that determinations were made.

4. Clinical research

If a patient is participating in a clinical research study, he/she must not only give the standard informed consent but must also sign a study-specific informed consent document. The research study and the consent form must be approved by whatever IRB has jurisdiction over research at the treating facility prior to initiation of research treatment or a compassionate use exception must be obtained from the IRB chair. 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 (OHSR) in the Office of the Deputy Director for Intramural Research (DDIR), National Institutes of Health (NIH).

V. DOCUMENTATION

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

1. The patient's name and identification number.
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 radiation therapy.
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.

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 and his/her title and department.
6. Signature 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 states:

1. That he/she has informed the patient of the nature of the procedure/treatment; the risks, complications, and expected benefits or effects of such treatment or refusal; the alternatives and their risks and benefits; and that the patient's/family's/caregiver's questions have been answered to the best of his/her understanding.
2. The type of radiation therapy recommended (external beam versus brachytherapy) should be specified. There should be a space to specify the type of brachytherapy procedure, if applicable.

The informing physician's statement is so important that the use of a form is recommended, although a detailed note in the consultation record would fulfill this requirement.

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

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