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The American College of Radiology will periodically define new practice guidelines and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice guidelines and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice guideline and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review, requiring the approval of the Commission on Quality and Safety as well as the ACR Board of Chancellors, the ACR Council Steering Committee, and the ACR Council. The practice guidelines and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice guideline and technical standard by those entities not providing these services is not authorized.

Revised 2011 (Resolution 39)\*

## **ACR–SIR PRACTICE GUIDELINE ON INFORMED CONSENT FOR IMAGE-GUIDED PROCEDURES**

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### **PREAMBLE**

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiation oncology 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 of 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.

Therefore, it should be recognized 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**

This guideline was revised collaboratively by the American College of Radiology (ACR) and the Society of Interventional Radiology (SIR).

Prudent and ethical medical practice requires close communication between the patient and the physician. The patient, or if the patient is unable to provide consent, the patient's legal representative and, when appropriate, the family, must have every opportunity to understand the treatment or procedure the patient is to receive and its reasonable alternatives, to have all questions answered, and to fully consent to the treatment and procedure. 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 or her professional judgment believes is appropriate to disclose to the patients. The degree of disclosure depends on perceptions of the physician in each case. The second legal standard is based on what a reasonable patient would want to know in the same or similar circumstances.

The legal trend is towards the "reasonable patient" standard, which usually requires greater and more detailed disclosure of information.

Informed consent is a process and not the simple act of signing a formal document. However, consent forms serve to document the physician's discussion 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 law.

## II. INDICATIONS

Informed consent and appropriate documentation should be obtained for, but not limited to, the following procedures:

1. Invasive diagnostic or therapeutic procedures.
2. Moderate sedation. For further information see the [ACR–SIR Practice Guideline for Sedation/Analgesia](#) [1].

Because of the documented low incidence of adverse events resulting from intravenous injection of contrast media, it may be exempted from the need for informed consent, but this decision should be based on state law and institutional policy, departmental policy, and local community practice.

## III. QUALIFICATIONS OF PERSONNEL

The physician or other health care provider who oversees or obtains informed consent should be familiar with the elements of informed consent, as well as the nature of the procedure being proposed, the risks of the procedure, the expected benefits of the procedure, and the alternatives to it.

## IV. RESPONSIBILITIES OF PERSONNEL

In all cases requiring informed consent, it is the physician or health care provider performing the procedure, or other qualified personnel assisting the physician, who should talk with the patient, explain the procedure, answer all questions, and arrange for appropriate documentation of informed consent. This documentation might take the form of an executed consent form, videotape, or a note in the patient's medical record.

When obtaining informed consent from the patient, the consent process requires face-to-face discussion of the procedure between the physician or other qualified health care provider and the patient. The consent process should include discussion of the anticipated benefits and potential risks of the procedure, as well as reasonable alternatives to the procedure. The patient should have the opportunity to ask questions and discuss the procedure. All of the patient's questions should be addressed. The

physician performing the procedure has the final responsibility for addressing the patient's concerns and answering the patient's questions. Consent should not be obtained in a coercive manner. The same standards apply to obtaining consent from the patient's health care representative or legally appointed guardian except that such consent may be reasonably obtained by telecommunication (see section V.B.7).

In institutions where department policy or legal advice based on state law requires informed consent for intravenous injections of contrast agents, ACR policy approves the obtaining of informed consent and injection of the contrast medium by qualified, credentialed technologists and nurses. For more information see the [ACR Practice Guideline for the Use of Intravascular Contrast Media](#) [2].

## V. SPECIFICATIONS AND DOCUMENTATION

Informed consent and appropriate documentation must be obtained prior to the initiation of any procedure that is likely to expose the patient to any significant risks and potential complications, except in emergency situations, as described in section V.C.

### A. Radiation Exposure

When obtaining informed consent for image-guided procedures that may be associated with higher levels of radiation (see Appendix A), an explanation of the likelihood and characteristics of deterministic injury should be included in the consent discussion prior to the procedure [3-4]. The estimated radiation dose received by the patient should be recorded in the patient's medical record following the procedure [5]. As noted in the [ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures](#) [6]: "If the cumulative air kerma at the reference point exceeds 3 gray, provisions should be made for follow-up of those areas for determination of radiation effects. (For specific classes of procedures, a different threshold for action can be established at individual institutions when supported by published literature.) In such circumstances there should be documentation in the medical record that the patient was advised of the potential for radiation injury to the skin and was given instructions for proper follow-up." The SIR–CIRSE Guidelines for patient radiation dose management recommend that follow-up should be performed if the cumulative air kerma at the reference point exceeds 5 gray [7].

### B. Protocol for Informed Consent for Elective Procedures

1. Before the proposed procedure is performed, the following will be explained to the patient or, if

the patient is unable to provide consent, to the patient's legal representative:

- a. The purpose and nature of the procedure or treatment.
  - b. The method by which the procedure or treatment will be performed.
  - c. The risks, complications, and expected benefits or effects of such procedure or treatment.
  - d. The risk of not accepting the procedure or treatment.
  - e. Any reasonable alternatives to the procedure or treatment and their most likely risks and benefits.
  - f. The right to refuse the procedure or treatment.
2. After the above items are explained and the physician or health care provider is satisfied that the patient understands the procedure and its possible consequences, the informed consent is executed and appropriately documented. This is most commonly done by having the patient sign a consent form.
  3. The name of the person or his or her designee performing the procedure must appear on the consent form prior to the signature by the patient.
  4. Documentation: A copy of the consent form(s) or videotape, if used, should be placed in the medical record. In all other situations a note should appear in the medical record that a discussion was held with the patient and that informed consent was obtained. The note should also include the date and time of the discussion, the content of the discussion, and an evaluation of the patient's understanding and response to information provided. A copy of any written informational materials given to the patient may also be included in the medical record.
  5. Since the patient must be able to understand the risks at the time he or she gives consent, medications that affect the sensorium should be kept at a minimum and ideally not given to the patient less than 4 hours prior to the patient's giving consent. Chronic pain medications are less likely to affect the sensorium. No patient should be deprived of adequate pain control for the purpose of obtaining consent.
  6. State statutes should be known and followed with regard to consent of those under legal age within that state. Some states have "emancipated

minor" or "mature minor" statutes that may apply.

7. Telephone consent: If consent is sought from the patient's health care representative, legally appointed guardian, or family member who cannot be physically present to sign the consent form before the procedure, informed consent by telephone may be obtained. The discussion should be documented on the consent form with a note that the consent was obtained by telephone. In such cases it is advisable to have the discussion witnessed by a second hospital staff member who signs the form as a witness.

#### C. Protocol for Informed Consent for Emergency Procedures

This protocol defines the scope of the emergency exception to the informed consent requirement when a patient needs immediate medical care and is unable to give informed consent.

1. When a delay in treatment would jeopardize the health of a patient, and the patient is unable to give informed consent, an exception to the requirement for obtaining informed consent from the patient is made.
2. If the patient is unable to consent and has a legally authorized representative who is available to consent, the treating physician must obtain the informed consent of the representative.
3. When informed consent cannot be obtained from the patient or from his or her legally authorized representative, the physician treating the patient should determine the immediacy of the need for treatment.
  - a. A physician may provide any treatment or perform any procedure immediately required to prevent serious disability or death or to alleviate great pain and suffering.
  - b. During the course of an operation or a procedure, a physician may perform any procedure that becomes necessary because of a condition discovered or arising during the operation or the procedure that presents an immediate threat to the life or the health of the patient.
4. The emergency exception to the requirement of informed consent does not extend to a conscious, competent adult patient, otherwise able to give his or her own informed consent, who has refused to consent to a treatment or a procedure.

- 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 impossibility 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 the determinations were made.

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## REFERENCES

- American College of Radiology. ACR-SIR Practice Guideline for Sedation/Analgesia. [http://www.acr.org/SecondaryMainMenuCategories/quality\\_safety/guidelines/iv/adult\\_sedation.aspx](http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/iv/adult_sedation.aspx). Accessed June 22, 2010, 2010.
- American College of Radiology. [ACR Practice Guideline for the Use of Intravascular Contrast Media](http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/dx/iv_contrast.aspx). [http://www.acr.org/SecondaryMainMenuCategories/quality\\_safety/guidelines/dx/iv\\_contrast.aspx](http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/dx/iv_contrast.aspx). Accessed June 15, 2010.
- Miller DL, Balter S, Cole PE, et al. Radiation doses in interventional radiology procedures: the RAD-IR study: part II: skin dose. *J Vasc Interv Radiol* 2003; 14:977-990.
- Miller DL, Balter S, Cole PE, et al. Radiation doses in interventional radiology procedures: the RAD-IR study: part I: overall measures of dose. *J Vasc Interv Radiol* 2003; 14:711-727.
- Miller DL, Balter S, Wagner LK, et al. Quality improvement guidelines for recording patient radiation dose in the medical record. *J Vasc Interv Radiol* 2004; 15:423-429.
- American College of Radiology. [ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures](http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/med_phys/management_fluoro_procedures.aspx). [http://www.acr.org/SecondaryMainMenuCategories/quality\\_safety/guidelines/med\\_phys/management\\_fluoro\\_procedures.aspx](http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/med_phys/management_fluoro_procedures.aspx). Accessed March 25, 2010.
- Stecker MS, Balter S, Towbin RB, et al. Guidelines for patient radiation dose management. *J Vasc Interv Radiol* 2009; 20:S263-273.
- Balter S, Miller DL, Vano E, et al. A pilot study exploring the possibility of establishing guidance levels in x-ray directed interventional procedures. *Med Phys* 2008; 35:673-680.
- Rosenthal LS, Mahesh M, Beck TJ, et al. Predictors of fluoroscopy time and estimated radiation exposure during radiofrequency catheter ablation procedures. *Am J Cardiol* 1998; 82:451-458.

## APPENDIX A

Procedures that have been associated with substantial radiation dose (Adapted from references [3-4,8-9].

- Transjugular intrahepatic portosystemic shunt creation

- Embolization (any location, any lesion)
- Stroke therapy
- Biliary drainage
- Visceral angioplasty and/or stent placement
- Stent-graft placement
- Chemoembolization
- Angiography and intervention for gastrointestinal hemorrhage
- Carotid stent placement
- Vertebroplasty
- Radiofrequency cardiac ablation
- Complex placement of cardiac electrophysiology devices
- Percutaneous coronary intervention

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