

ACR–SIR–SPR PRACTICE PARAMETER ON INFORMED CONSENT FOR IMAGE-GUIDED PROCEDURES

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PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic 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 considering 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 variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and 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 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*, 831 N.W.2d 826 (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

This practice parameter was revised collaboratively by the American College of Radiology (ACR), the Society of Interventional Radiology (SIR), and the Society for Pediatric Radiology (SPR).

The informed consent process for a procedure must include the full participation of both the patient (and/or patient's legal representative) and physician or nonphysician provider to facilitate true shared decision making [1,2]. Successful open dialogue between physician or nonphysician provider and patient may be challenging for several reasons, including, but not limited to, cognitive impairments, language barriers, stress, disparate health literacy and the complexity of the procedure, and other factors unique to each clinical encounter [3].

Prudent and ethical medical practice requires close communication between the patient and the physician or nonphysician provider. If the patient is unable to provide consent, the patient's legal representative or, in the case of a minor, the patient's parent(s) or legal guardian, represents the patient in the consent process. The patient or representative and, when appropriate, the patient's family, must have every opportunity to understand the proposed treatment or procedure and its reasonable risks, benefits, and alternatives; to have all questions answered; and to consent to the treatment and procedure. The degree of disclosure required for a valid consent varies, but there are 2 generally recognized legal standards. The first is measured by what a reasonable physician or nonphysician provider in their professional judgment believes is appropriate to disclose to the patient. The degree of disclosure depends on perceptions of the physician or nonphysician provider in each case. The second legal standard is based on what a reasonable patient would want to know in the same or similar circumstances. It is important for each provider to understand the applicable state requirements and exercise appropriate disclosure based on those standards.

Informed consent is a process of ongoing dialogue/discussion and is not the simple act of signing a formal document. Consent, even when granted by the patient in writing, may reasonably be withdrawn at any time, hence the need for ongoing dialogue. Consent must be documented in the medical record, and consent forms may serve to document the physician's or nonphysician provider's discussion with the patient. These forms usually contain the patient's or representative's signature authenticating consent to the treatments or procedures that will be performed. Another acceptable method of documentation is a physician or nonphysician provider note in the medical record indicating that the discussion took place and that the consent of the patient was obtained; however, this method is less defensible from a legal standpoint because it is only a one-party affirmation of that consent discussion. Informed consent with appropriate documentation must follow institutional policies and procedures and comply with applicable state law.

When obtaining informed consent, the consent process requires discussion of the procedure between the physician or other nonphysician provider and the patient. Asking the patient directly about their expectations of the procedure will contribute to a meaningful dialogue and improved shared decision making and has been shown to increase patient understanding [4]. The same standards apply to obtaining consent from the patient's health care representative or legally appointed guardian (see Section IV.B.6). In the case of a minor, consent should be obtained from the patient's parent(s) or guardian per institutional and/or state guidelines. In some institutions, materials such as videos, mini courses, or pamphlets are used to educate the patient about their condition and the procedure needed, but these do not obviate the necessity for direct physician or nonphysician provider patient discussion. The consent process should include discussion of the anticipated benefits and potential risks of the procedure, as well as reasonable alternatives to the procedure [5]. The patient or representative should have the opportunity to ask questions and discuss the procedure, and all questions should be addressed. The Agency of Healthcare Research and Quality (AHRQ) and the National Quality Forum (NQF) recommend asking the patient to restate in their own words what they were told during informed consent [6]. Known as the "teach-back-method," this step constitutes safe practice and may be especially effective in patients with an unknown level of health literacy. The physician or nonphysician provider performing the procedure has the final responsibility of ensuring that all concerns and questions are addressed satisfactorily. Consent cannot be obtained in a coercive manner.

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 Parameter for Minimal and/or Moderate Sedation/Analgesia](#) [7])

Some minor procedures have a documented low incidence of adverse events (eg, intravenous (IV) injection of contrast media). These procedures may be exempted from the need for formal or authenticated informed consent, but the decision not to obtain informed consent in these circumstances should be consistent with state law, institutional policy, departmental policy, and local community practice.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Qualifications of Personnel

The physician or nonphysician provider who oversees or obtains informed consent should be familiar with the elements of informed consent as well as with all aspects of the procedure being proposed, the risks of the procedure, the expected benefits of the procedure, and reasonable alternatives to the proposed procedure.

B. Responsibilities of Personnel

The physician or nonphysician provider performing the procedure or other qualified personnel assisting them should talk with the patient or representative, explain the procedure, answer all questions, and arrange for appropriate documentation of informed consent, consistent with state law, institutional policy, departmental policy, and local community practice regarding specific requirements. This documentation might take the form of an executed consent form, videotape, or a note in the patient's medical record. In institutions in which department policy or legal advice based on state law requires informed consent for IV 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–SPR Practice Parameter for the Use of Intravascular Contrast Media](#) [8].

IV. 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 potential complications, except in emergency situations, as described in Section IV.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 [9-12]. Radiation dose may be determined and recorded in many different ways [13-15]. The [ACR–AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures](#) [16], the SIR–CIRSE Guidelines for patient radiation dose management [17], and the National Council on Radiation Protection & Measurements (NCRP) [11,12,18] indicate that when a cumulative air kerma at the reference point exceeds 5 Gy, special follow-up precautions should be instituted. Therefore, when a given procedure can be reasonably anticipated to approach this level (see Appendix A for a list of potentially high-dose procedures), a discussion of deterministic injury should occur as part of the consent process. Special consideration is required for the pregnant patient regarding fetal exposure [19-21], and it should generate a discussion of potential effects of radiation exposure to the fetus as part of the consent process.

B. Protocol for Informed Consent for Elective Procedures

Patient-centered informed consent is accomplished by discussing the procedure or treatment in the context of the patient's culture or values and desired outcome [2]. If a language barrier is present, consider using an interpreter or written translation of documents to ensure the patient is able to understand the information provided and consent to the proposed procedure. Questions and concerns should be elicited, and time allowed for discussion with family members. Consent must be voluntarily provided, and the patient has the

right to refuse to consent or withdraw consent.

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
2. After the above items are explained and the physician or nonphysician 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 or representative sign a consent form, along with the physician or nonphysician provider and a witness, when required. Should a translator be used, it should be documented per institutional policy.
3. Documentation: A copy of the consent form(s) or videotape, if used, should be placed in the medical record. If a video, brochure, or other standardized materials was used in the consent process, this can be acknowledged in the documentation.
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.
4. Because the patient must be able to understand the risks at the time consent is given, medications that affect the sensorium should be kept at a minimum, and ideally not administered within 4 hours prior to the consent process. 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.
5. A physician or nonphysician provider should follow state law applicable to obtaining consent from minors.
6. Telephone/video conferencing/telehealth consent: If consent is sought from the patient, patient's health care representative, legally appointed guardian, or family member who cannot be physically present to sign the consent form before the procedure, then informed consent should include documentation of methodology and proper witnessing as stated in state law, institutional policy, departmental policy, and local community practice.
7. For procedures that may need to be repeated over the course of the patient's health condition, consent to perform the procedure "as medically indicated" during a specified period of time might be appropriate if permitted by, and done in accordance with, institutional policies and procedures and applicable law.

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 but 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 and there is no legal representative available, an exception to the requirement for obtaining informed consent from the patient applies.
If the patient is unable to consent and has a legally authorized representative who is available, consent should be obtained from the representative.
2. When informed consent cannot be obtained from the patient or from their legally authorized

representative, the physician-led team 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.
3. The emergency exception to the requirement of informed consent does not extend to a conscious adult patient with decision-making capacity who is otherwise able to give informed consent, who has refused to consent to a treatment or a procedure.
 4. 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. In addition, documentation should comply with all relevant institutional and/or government guidelines.

V. ACKNOWLEDGEMENTS

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Writing Committee – members represent their societies in the initial and final revision of this practice parameter

ACR

Elizabeth Ann Ignacio, MD, Chair

Claire Kaufman, MD

Matthew P. Lungren, MD, MPH

Derrick Siebert, MD

SIR

Lynn A. Brody, MD, FSIR

A. Kyle Jones, PhD

Michael S. Stecker, MD, FACR, FSIR

SPR

Ranjith Vellody, MD

Jonathon Weber, MD

Committee on Practice Parameters – Interventional and Cardiovascular Radiology

(ACR Committee responsible for sponsoring the draft through the process)

Drew M. Caplin, MD, Chair

Margaret Hsin-Shung Lee, MD, FACR

Chaitanya Ahuja, MBBS

Mary Lee Jensen, MD, FACR

Douglas M. Coldwell, MD, PhD

Claire Kaufman, MD

Mandeep S. Dagli, MD

Dennis Kay, MD, FACR

Kevin W. Dickey, MD, FACR

Kennith F. Layton, MD, FACR

Meredith J. Englander, MD

M. Victoria Marx, MD

C. Matthew Hawkins, MD

Christopher D Yeisley, MD

Committee on Practice Parameters – General, Small, Emergency and/or Rural Practices

(ACR Committee responsible for sponsoring the draft through the process)

Candice Johnstone, MD, Chair

Charles E. Johnson, MD

Lynn Broderick, MD, FACR

Steven E. Liston, MD, MBA, FACR

Justin P. Dodge, MD

Derrick Siebert, MD

Brian D. Gale, MD, MBA

Samir S. Shah, MD

Rachel Gerson, MD,

Jennifer L. Tomich, MD

Carolyn A. Haerr, MD

Committee on Practice Parameters – Pediatric Radiology

(ACR Committee responsible for sponsoring the draft through the process)

Terry L. Levin, MD, FACR, Chair

Jane Sun Kim, MD

John B. Amodio, MD, FACR

Jennifer A Knight, MD

Jesse Berman, MD

Jessica Kurian, MD

Tara M. Catanzano, MB, BCh

Matthew P. Lungren, MD, MPH

Harris L. Cohen, MD, FACR

Helen R. Nadel, MD

Kassa Darge, MD, PhD

Erica Poletto, MD

Dorothy L. Gilbertson-Dahdal, MD

Richard B. Towbin, MD, FACR

Lauren P. Golding, MD

Andrew T. Trout, MD

Safwan S. Halabi, MD

Esben S. Vogelius, MD

Jason Higgins, DO

Alan H. Matsumoto, MD, FACR, Chair, Commission on Interventional and Cardiovascular Radiology

Robert S. Pyatt, Jr., MD, FACR, Chair, Commission on General, Small, Emergency and/or Rural Practice

Richard A. Barth, MD, FACR, Chair, Commission on Pediatric Radiology

David B. Larson, MD, MBA, Chair, Commission on Quality and Safety

Mary S. Newell, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee

C. Matthew Hawkins, MD, Chair

Matthew P. Lungren, MD, MPH

Richard B. Gunderman, MD, PhD, FACR, Co-Chair

Alan H. Matsumoto, MD, FACR

Comments Reconciliation Committee

Richard A. Barth, MD, FACR

Mary S. Newell, MD, FACR

Lynn A. Brody, MD, FSIR

Robert S. Pyatt, Jr., MD, FACR

Drew M. Caplin, MD

Adam V. Ratner, MD, FACR

Richard Duszak Jr., MD, FACR

Erick M. Remer, MD, FACR

Elizabeth A. Ignacio, MD

Michael I. Rothman, MD, FACR

Candice Johnstone, MD

Derrick Siebert, MD

A. Kyle Jones, PhD

Michael S. Stecker, MD, FACR, FSIR

Claire Kaufman, MD

Ranjith Vellody, MD

Amy L. Kotsenas, MD, FACR

Jonathon Weber, MD

David B. Larson, MD, MBA

Kevin Wong, DO

Terry L. Levin, MD, FACR

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Appendix A

Procedures that have been associated with substantial radiation dose (Adapted from references [[9](#),[10](#),[22](#)])

- 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
- Vertebral augmentation
- Radiofrequency cardiac ablation
- Complex placement of cardiac electrophysiology devices
- Percutaneous coronary intervention