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**ACROinsights – Informed Consent for Radiation Oncology**

The goal of this series of articles is to ensure that radiation oncologists are aware of and provided with the knowledge to ensure day-to-day processes are being addressed in a compliant manner. This installment will discuss informed consent to assist physicians and practices with the tools necessary to ensure the required information is communicated to the patient. The information contained within this ACROinsights article is meant as general guidance and is not intended to replace appropriate legal or authoritative guidance.

**Defining Informed Consent**

Patients seen in radiation oncology (RO) facilities have often been cared for by other oncology and non-oncology health care providers. They often arrive with varying levels of information or understanding about radiation treatments, and what they should expect from radiation, as it relates to the nature and/or status of their disease. As active participants in decision-making, it is critical that ROs and their staff be sensitive to these concerns. Some patients will easily or quickly agree to the treatment plan proposed to move the process along expeditiously, while others will pose many questions or request time to ponder their decisions. Regardless of the patient and caregiver issues, the process of acquiring informed consent is not simply that of obtaining an executed document. Instead, it is the continuum of a process provided by the physician and support staff to provide information regarding anticipated risks and benefits of treatment, responding to questions and providing understandable information so the patient, appropriate caregivers, or their legal representative, can make their final decisions based on the best available information.

The National Cancer Institute[i] defines informed consent as "*A process in which patients are given important information, including possible risks and benefits, about a medical procedure or treatment, genetic testing, or a clinical trial. This is to help them decide if they want to be treated, tested, or take part in the trial. Patients are also given any new information that might affect their decision to continue. Also called consent process.*"

According to the American Medical Association's *Code of Medical Ethics*, Chapter 2: "Opinion on Consent, Communication & Decision Making"[ii],

> The process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention. In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decision-making capacity or declines to participate in making decisions), physicians should:
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> (a) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision.
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> (b) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about:
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> (i) the diagnosis (when known);
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> (ii) the nature and purpose of recommended interventions;
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> (iii) the burdens, risks, and expected benefits of all options, including forgoing treatment.
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> (c) Document the informed consent conversation and the patient's (or surrogate's) decision in the medical record in some manner. When the patient/surrogate has provided specific written consent, the consent form should be included in the record.

Informed consent of pediatric patients, under age 18, requires the consent by the parent(s) or legal guardian. It is also recommended that the discussion and agreement about radiation treatments include the pediatric patient, although this can and will vary depending on their age and comprehension level. Inclusion of the pediatric patient

in the full process will often assist in how well they participate in the day-to-day routine and processes for the course of treatment.

Patients participating in a clinical research study must provide signed consent of both the standard facility informed consent document and the study-specific informed consent The Institutional Review Board (IRB) that has been granted jurisdiction, must first approve the clinical research study and any associated informed consent forms for the facility where the patient will be treated.

**What Radiation Oncology Services Require Informed Consent?**

Patients undergoing radiation treatments will receive a variety of services during their care. Some services may be more complex or invasive than others. According to the *ACR–ARS Practice Parameter on Informed Consent Radiation Oncology*, revised 2022[iii],

> Informed consent must be obtained and appropriately documented prior to the initiation of any complex medical treatment, including, but not limited to, the following procedures:
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> 1. Imaging for simulation of radiotherapy treatment setup including field placement and/or treatment planning and any associated procedures, such as use of contrast agents and tattoo placement
>
> 2. Radiotherapy treatment including external beam radiation therapy, radiopharmaceutical therapy, high dose-rate or low dose-rate brachytherapy, radiopharmaceutical therapy, etc.
>
> 3. Administration of conscious sedation

The ACR does explain there are situations in which there may be exceptions to the informed consent rule, including: emergency situations; the patient specifically requests not be informed regarding certain aspects of their diagnosis, and any risks from the treatment or management; and, when the attending radiation oncologist determines that disclosure of certain information may have a substantially negative impact on the patient's health. These circumstances would be exceeding rare and should be adequately documented.

Whenever possible, a radiation oncologist should obtain the informed consent. Alternatively, it can be performed by a licensed physician who fully understands the procedure or treatments under consideration. While certain clinical staff members may be able to assist in the process and verify that the patient understands the information provided to them, it is ultimately the radiation oncologist's responsibility to ensure the information presented is accurate and understood by the patient and/or their legal representative.

With the expansion of telehealth for many services, the process for obtaining informed consent is still best carried out in person. In circumstances when the patient's legal representative or the radiation oncologist who will be performing the procedure is not able to be physically present, informed consent may be possible by telecommunication. The necessity for use of this form of communication should be documented. It is important for radiation oncologists to be familiar with their state's regulations regarding informed consent through telecommunication. Typically, there must be some two-factor verification of the patient and participation by a staff member to witness and document the consent.

**Components of Informed Consent**

The most important component of informed consent is that the information provided is presented in a manner that allows for the patient's capacity to understand, and the patient's willingness to accept or refuse treatment, without coercion. It is recommended that informed consent forms should be written at the 6$^{th}$-8$^{th}$ grade reading level. Complex technical terminology, abbreviations and acronyms should be avoided.

As specified in the *ACR Practice Parameter on Informed Consent* the physician must inform the patient or legal representative of the following as part of the process:

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, adjuvant, or palliative)
2. The nature of the proposed treatment, the parts of the body to be treated (including laterality when relevant), and the method by which the treatment will be given
3. The expected side effects and/or complications that a prudent practitioner or patient would find meaningful including:
    a. Complications or side effects that occur commonly [i.e., skin changes, fatigue, hair loss, and effects specific to area of body treated] and are likely to occur
    b. Complications or side effects that may be rare but serious if they do occur and that occur with sufficient frequency that a reasonable patient would want to be informed 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

There are other scenarios in which additional review of pertinent impact and information should be provided to the patient as pertinent to their situation. Patients who will undergo implantation or instillation of radioactive sources should have the potential risks to members of their family and others they may encounter reviewed to ensure that they understand, and agree to comply with any restrictions. Patients of childbearing age should have the implications of radiation treatments on their fertility reviewed. Patients with pacemakers or other implanted devices which may be affected by radiation should have this reviewed as part of the informed consent process. Lastly, patients should understand the potential impacts that any previous radiation may have on the new treatment course.

Documentation of the informed consent should be maintained in the patient's medical record and may or be required to include the materials or information provided to the patient or legal representative. The document should include two methods identifying the patient, the name of the physician or entity performing the procedure(s), a statement with the patient's name or "myself" listed as authorizing the treatment, a second statement in the first person of the patient indicating the treatment, side effects, risks, and alternatives have been explained to the patient or person who signs the form. Additional first-person statements to consider including, if applicable, authorization of tattoos, photos for documentation, risk of radiation to pregnancy, and there may be additional staff or physicians who may participate in the care of the patient. A statement indicating that the patient or legal representative has been offered the opportunity to ask questions, and that those questions have been answered should be included. States or institutions may also have additional or other defined criteria for what must be included or part of the documentation for informed consent.

The informed consent form should provide space for the patient or their legal representative to sign, identify their relationship to the patient and the date they signed. Additionally, if there is a witness or translator, there should be space for their signatures and identification. If the patient did not sign the form, there should be a reason stated within the form.

Separately the radiation oncologist should document that they provided this information to the patient or legal representative, they were able to ask and have their questions answered, what kind of radiation was proposed, if there were any special considerations or requests to the amount of information provided to the patient, and what lack of any testing may mean to the course of treatment.

**The Take Home Message**

Informed consent involves more than just a signature agreeing to radiation treatment. It is important that the information is presented in a manner with terminology that allows for the patient's (or legal representative)

capacity to understand and the patient's willingness to accept or refuse treatment, without coercion. Due to the long-term implications of radiation to the body, the understanding and comprehension of the patient and/or their legal representative must be assured prior to any procedures being performed. It is the responsibility of the radiation oncologist to ensure the documentation, presentation and acquisition of consent is accurately and appropriately obtained and documented in the medical record.

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[i] National Cancer Institute, NCI Dictionaries, https://www.cancer.gov/publications/dictionaries.

[ii] American Medical Association's *Code of Medical Ethics*, Chapter 2: "Opinion on Consent, Communication & Decision Making", https://www.ama-assn.org/system/files/2019-06/code-of-medical-ethics-chapter-2.pdf

[iii] *ACR–ARS Practice Parameter on Informed Consent Radiation Oncology*, revised 2022, https://www.acr.org/-/media/ACR/Files/Practice-Parameters/informedconsent-ro.pdf