

# Standards for Patient Consent Particular to Radiology



Board of the Faculty of Clinical Radiology  
The Royal College of Radiologists

The Royal College of Radiologists  
38 Portland Place  
London W1B 1JQ

Telephone 020 7636 4432  
Fax 020 7323 3100

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Royal College of Radiologists, London.  
Email: enquiries@rcr.ac.uk

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# RCR Standards

The Royal College of Radiologists, a registered charity, exists to advance the science and practice of Radiology and Oncology.

It undertakes to produce standards documents to provide guidance to radiologists and others involved in the delivery of radiological services with the aim of defining good practice, advancing the practice of radiology and improving the service for the benefit of patients.

The standards documents cover a wide range of topics. All have undergone an extensive consultation process to ensure a broad consensus, underpinned by published evidence, where applicable. Each is subject to review four years after publication or earlier, if appropriate.

The standards are not regulations governing practice but attempt to define the aspects of radiological services and care which promote the provision of a high quality service to patients.

## Dean's Foreword

Development of advice in respect of consent is an essential part of the recognition of patient autonomy and right to choose. All radiologists and indeed all doctors recognise the need to fully involve patients in decisions about their care. Whenever possible, you must be satisfied before you provide treatment or investigate a patient's condition that the patient has understood what is proposed and why, is appropriately informed about the balance between risk and benefit, and has given consent.

The advice provided in this document is deliberately generic, rather than prescriptive. We have not provided lists of procedures which require written consent, nor those where implied consent would be appropriate and sufficient. In each case where you provide care, you will need to make a judgement on the basis of the nature of the procedure, level of risk versus the potential benefit, and your understanding of the needs of the patient. In making this judgement, you must ensure that:

1. the patient has the right information to make a decision
2. the information has been presented in a way that the patient can understand
3. the patient has shared in the process of decision-making and agrees with the outcome.

Above all, 'consent' is involving patients in decisions made about their care, and communicating information effectively, thus ensuring that decisions made about patient care are made with the patient, rather than for the patient.

The College is very grateful to members of the Faculty of Clinical Radiology's Standards Sub-Committee for their work on this document and, in particular, to Dr Rob Manns who is responsible for much of its drafting. The College also much appreciates Dr P Dubbins' contribution to the development of this standard during his tenure as Dean and Vice- President of the Faculty of Clinical Radiology.

**Dr G Markham**

Vice-President and Dean

Faculty of Clinical Radiology

The Royal College of Radiologists

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# 1 Introduction

Successful relationships between patients and doctors depend upon trust. Patients are becoming increasingly well informed and are rightly demanding more involvement in decisions relating to their medical care. Consent to treatment is an integral part of this involvement and underpins the trust that the patient places in his or her doctor and the confidence that the patient has in the process of care. The principle of patient consent requires the doctor to respect the patient's autonomy and right to decide whether to undergo any medical investigation or intervention.

## 2 Consent

Except in emergencies, in circumstances when consent cannot be obtained, patient consent to treatment is a legal requirement for medical care. It is good practice to ensure that consent is given in the appropriate environment, in the proper manner and in the presence of appropriate and relevant information.

For consent to be valid, the patient must be informed about the treatment concerned, competent to give consent and able to give it voluntarily.

Effective communication is key to enabling patients to make informed decisions. Patients must be given information in a timely manner and in a way they can understand to enable them to exercise their right to make an informed decision about their investigations and treatment. The initial consent to a radiological examination or intervention should be obtained by the referring clinician in consultation with the patient through explanation of the reasons for the examination or intervention requested.

### **'Prudent doctor' / 'prudent patient'**

The courts used to apply the 'prudent doctor' principle – i.e., where the doctor weighs the risk of a certain complication occurring against the risk resulting from putting a patient off necessary treatment. Complications with an extremely low incidence were generally considered not worth mentioning, unless the particular complication would have serious consequences for the patient. In recent years, however, there has been a shift towards the 'prudent patient' model, prevalent in the USA. The emphasis of this model is on what the average 'prudent patient' would want to know about potential risks and treatment options.

### **Implied consent**

Radiologists need to be able to explain to patients the potential risks and benefits of particular radiological examinations and procedures. In the majority of examinations the risk involved will be very low, and in these cases the implied consent of the patient will be obtained at the time of the examination by other members of the radiological team on behalf of the reporting or supervising radiologist. The patient's actions at the time of the examination will indicate whether the patient is content for the examination or other procedure to proceed.

### **Express consent**

Judgement is required as to when express consent must be obtained and the degree of detail appropriate to a discussion with a patient about a particular radiological examination. Individual

radiologists will, of course, vary the particulars presented in a discussion about, for example, a barium enema examination with different patients. This variation should not, however, detract from the consent required from the patient before the examination is initiated. Express consent can be given by the patient, either verbally or in writing

### **Interventional / invasive procedures**

Interventional or invasive radiological procedures require particular attention in obtaining the express consent of the patient. In a planned procedure, the patient should receive information, verbally or in writing, in sufficient time prior to the procedure to consider it and to consult others if they so wish. The patient should then have their informed consent confirmed at a separate discussion with the radiologist performing the procedure. This discussion should occur close to when the procedure is to take place but still allow time for further open consultation, if it is needed. This further consultation should happen outside the immediate environment of the procedural room and, preferably, on a hospital ward, in an office or in an outpatient facility.

### **Emergency and planned procedures**

Emergency, unplanned procedures require the judgement of the individual radiologist as to the time and opportunity available for obtaining informed consent.

With planned procedures, consideration should be given to asking the patient to sign a written consent form for those examinations and procedures which are recognised to be more complex to undertake or which potentially carry a more serious risk of complication. Sometimes, however, undue emphasis is placed upon the act of signing a consent form. Such forms are helpful and may be required by your employing Trust, but they are not enough on their own. Most important in the process of informed consent are: 1) having a detailed discussion with the patient, and 2) clearly establishing that the patient has sufficient information to make an informed decision to proceed with the procedure concerned.

### **Written consent**

The GMC suggests that written consent should be taken in cases where:

- The treatment or procedure is complex and involves significant risk and / or side effects
- Providing clinical care is not the primary purpose of the investigation or procedure (in particular, where the examination or procedure is for non therapeutic purposes)
- There may be significant consequences for the patient's employment, social or personal life
- The treatment is part of a research programme. Written consent for some procedures is also required by the *Mental Health Act* and the *Human Fertilisation and Embryology Act*.

Consent must be freely given, without pressure from anyone. If consent is given under duress, then that consent will be deemed invalid. If a patient asks for your opinion as a doctor involved in their care, then this should be honestly, accurately and clearly given. This advice should be based on what is in the best interest of the patient, with due acknowledgement of the risk and benefit involved.

## 3 Documentation of consent

You should be prepared to explain and justify your involvement in the consent obtained. This may be required at a later date and should be supported by appropriate, contemporaneous documentation prepared at the time the consent was given.

### Providing sufficient information

Patients have a right to information about their condition and the treatment options available to them. The amount of information you provide to each patient will vary, according to factors such as the nature of the condition, the complexity of the examination, the risks associated with the examination or procedure, the patient's own wishes, and the patient's age and mental state.

### Key pieces of information

The GMC details twelve key pieces of information that patients should be given:

- (1) Details of the diagnosis and prognosis, and the likely prognosis if the condition is left untreated;
- (2) Uncertainties about the diagnosis, including options for further investigation prior to treatment;
- (3) Options for treatment or management of the condition, including the option not to treat;
- (4) The purpose of a proposed investigation or treatment; details of the procedures or therapies involved, including subsidiary treatment such as pain relief; how the patient should prepare for the procedure; and details of what the patient might experience during or after the procedure, including common minor and rare serious side effects;
- (5) For each option, explanations of the likely benefits and the probabilities of success; and discussion of any serious or frequently occurring risks, and any lifestyle changes which may be caused or necessitated by the treatment;
- (6) Advice about whether a proposed treatment is experimental;
- (7) How and when the patient's condition and any side effects will be monitored or re-assessed;
- (8) The name of the doctor who will have overall responsibility for the treatment and, where appropriate, the names of senior members of the doctor's team;
- (9) Whether doctors in training will be involved, and the extent to which students may be involved in an investigation or treatment;
- (10) A reminder that patients can change their minds about a decision at any time;
- (11) A reminder that patients have a right to seek a second opinion; and
- (12) Where applicable, details of costs and charges which the patient may have to meet.

### Information about risk and risk / benefit

Many radiological procedures carry a risk. These include radiation risks, as well as specific risks associated with more invasive interventional procedures. Patients should be informed of the details of the process of an examination, any expected discomfort and its likely duration, and also the risks of morbidity and of mortality. If several radiologists within a department undertake similar interventional procedures, it is useful and valuable to establish common views on the relative risks and benefits of these procedures to clarify matters for individual patients and referring clinicians. Leaflets in a clear and understandable form are valuable for communicating such factual detail. The Royal College of Radiologists web site ([www.rcr.ac.uk](http://www.rcr.ac.uk)) has information leaflets on specific radiological examinations written and designed in collaboration with the RCR Clinical Radiology Patients' Liaison Group (PLG). These leaflets can be adapted for local departmental use. In addition, on the public pages of the RCR website *Goingfora.com*, a virtual radiological clinic, can be found. It is

a useful, easy to access information source for patients.

Complex radiological procedures, for example some CT studies, may require a significant radiation dosage. Literature from the National Radiological Protection Board, now the Radiation Protection Division of the Health Protection Agency ([www.hpa.org.uk/radiation](http://www.hpa.org.uk/radiation) <<http://www.hpa.org.uk/radiation>> ) is available which explains the typical effective radiation doses from diagnostic medical exposure and their risks, and provides comparative information for exposure to natural background radiation encountered when, for example, flying in an plane. The clinical radiologist will already have reviewed the clinical indication for the examination in order to ensure that risk / benefit has been properly evaluated. However, the patient may wish to discuss further the necessity for or the desirability of the radiation exposure involved. Additional information may be needed. The time and effort of the radiological team in discussing these aspects of radiological care require special workload and timetabling arrangements within the imaging department.

It is important to emphasise that patients cannot give valid consent unless they understand what they have been told. The presentation of information to patients must take account of the patient's values, culture, language, background, age and mental ability.

Patient literature should give clear information. Ideally, this resource should be available to the patient to take away to read and discuss with friends and family prior to discussion with the doctor or other medical professional obtaining consent.

Time for open discussion with patients about the balance of risk versus benefit, and alternative forms of investigation and treatment is essential to the process of obtaining informed consent.

The PLG has suggested that examinations or procedures having a known potential risk of complications of the order of >1:2000 should be brought to the attention of the patient when seeking consent. Details about possible complications and their relative risk should be included in patient literature and, where possible, this literature should contain evidence of local audits and standards, as well as more generic information. This information will aid in the discussion of potentially distressing points.

### **Patient-initiated non-informed consent**

If patients refuse to discuss potentially adverse events, gentle questioning, support and encouragement may be needed to make certain that no discussion is really what they want. It is appropriate to document this in the patient's record. If the patient is insistent and consistent in refusing to discuss potential adverse effects or complications from a proposed examination or intervention, then this patient initiated non-informed consent needs to be recorded at that time in the patient's case notes. It is advised that in such circumstances the patient's decision is witnessed by another team member who records his or her understanding of this discussion for the case notes.

Involving other members of the health care team should always be considered in supporting the patient. The patient may also wish relatives to be present. The doctor obtaining consent must allow sufficient time for questions from the patient and must answer them fully and honestly. Patients must have adequate time to consider the information they are given before they have to make a decision as to their consent.

## **4 Patient autonomy**

A doctor should find out what patients want to know and ought to know and respect the patient's decision. There should be dialogue resulting in clarity of objectives and understanding between patient and doctor.

## 5 Delegation

The delegation of responsibility for initial patient consent consultation to an appropriate member of the clinical radiological team may improve accessibility while maintaining a high standard of care. This should be in the best interest of the patient. The person to whom the role of obtaining initial consent is delegated must be suitably trained and qualified, have sufficient knowledge of the proposed investigation or treatment and understand the risks involved. They should adhere to GMC guidance on consent, as they are acting on the behalf of a doctor. The final confirmation of informed consent at the time of the examination, however, remains the responsibility of the doctor involved in the radiological examination or intervention.

## 6 Intimate examinations

Intimate examinations require particular attention and understanding to establish trust and mutual confidence between patient and doctor. The appropriate setting, the need for privacy, preservation of the patient's dignity and respect for his or her personal beliefs will all influence this type of examination. Express consent, either verbally or in writing, should be obtained for intimate examinations and serious consideration should be given to the need to provide a chaperone.

## 7 Consent for the use of imaging in teaching and training

Imaging is now central to the practice of medicine, and training doctors to interpret medical images is, therefore, crucial to the provision of high quality care. This is, of course, central to the training of clinical radiologists. In the development of training programmes, and the use of images to underpin that training, departments of clinical radiology must ensure that patient images are, wherever possible, anonymised to ensure patient confidentiality. This, of course, is not always possible and frequently not desirable, particularly when the process of anonymisation could compromise patient care and safety. This may occur in "live case" situations where teaching is opportunistic, such as during reporting sessions, during the course of MDTM's, or during the review by colleagues and trainees of difficult cases.

The College supports the concept of "anonymise or ask" proposed by the Patient Information Advisory Group (PIAG) and recognises that both processes are intended to be thorough. However, processes for eliciting consent for the use of images in teaching radiologists, other professionals and medical students are not yet well established. Departments of clinical radiology and NHS Trusts need to provide information about the nature of the training environment to patients in a number

of ways. This will include posters within the hospital and the department, information contained within patient appointment letters, patient information sheets and general information provided by the Trust. Every effort should be made 1) to ensure that patients are aware of the information and 2) to communicate the nature and importance of teaching in clinical practice in ways understandable by the patient. Consultation with the Trust Caldicott Guardian will ensure that processes of anonymisation and consent are robust.

In order to adhere to guidance from PIAG and the National Care Records Board, further development of the consent process will be needed in light of the advent of the electronic patient record and PACS.

## 8 Establishing capacity to make decisions

An adult person is adjudged competent to give consent if he or she can comprehend information which has been presented in a clear way, believe it and retain it long enough to weigh it up and make a decision. A patient's decision may seem illogical, but this in itself is not evidence that the patient lacks competence. In such cases, you should review with the patient the reasons for their decision and establish that you have given to them all the relevant information. The patient with a fluctuating level of attention and concentration should be given any assistance that may help them to make an informed decision. *Particular care should be taken when sedative drugs have been administered to the patient.* It is necessary to record the patient's decision when they are competent and establish that their view is consistently held and can be relied upon. If in doubt, seek legal advice. For patients who are mentally incapacitated, provided they willingly comply with treatment you may carry out an investigation or intervention that you judge to be in their best interests. However, if they are unwilling to comply, then you should seek legal advice before proceeding.

## 9 Children and consent

You must assess a child's capacity to give consent before you attempt to obtain it. In general, a competent child will be able to understand the nature, purpose and possible consequences of the proposed procedure, as well as the consequences of non-treatment. Competent children under the age of 16 years may refuse treatment, but a person with parental responsibility (or the court) may then authorise investigation or treatment which is in the child's best interest. This position is different in Scotland where those with parental responsibility cannot authorise procedures which a competent child has refused. If in doubt, you should seek legal advice.

## 10 Refusing consent

If a patient is competent to give consent, he or she is entitled to refuse consent, no matter how illogical their decision may seem. If the consequences of their refusal are potentially serious, you should discuss this decision with the patient to clarify the situation. In particular, you need to establish that they have understood the information they have been given, their condition, the proposed treatment and any possible side effects. A patient's refusal to treatment may appear irrational but that is again, in itself, no reason to question their competence. However, a refusal might lead you to further investigate their mental capacity if, for example, it were at odds with previous decisions they had made. *When consent is refused, it should be recorded contemporaneously in the presence of a third party and placed in the patient's notes.*

## 11 Withdrawing consent

Patients can withdraw their consent at any time. They need to be competent to do so. If a patient asks you during a procedure to stop, you should temporarily do so, find out their concerns and explain the consequences of not proceeding. Establishing the competence of a patient during a procedure is difficult; pain, shock and medication they have received may have altered their capacity to make rational decisions. However, if the patient is competent and decides to withdraw their consent, you must respect their wishes and stop the treatment providing that, in so doing, they will not come to immediate harm.

## 12 Emergencies

In an emergency, when consent cannot be obtained, you may give medical treatment to anyone who needs it, provided the treatment is limited to what is immediately necessary to save life and avoid significant deterioration in the patient's health. You should tell the patient what has been done and why, as soon as the patient is sufficiently recovered to understand.

## 13 Consent to screening

Screening for disease can be an important tool in effective clinical care. The uncertainties involved in the screening process may, however, be significant, for example the risk of false positive or false negative results. The doctor involved must ensure that any patient considering screening can make a properly informed consent decision. The information outlined to the patient should include the purpose of the screening and the uncertainties and risks associated with it. Any significant medical, social or financial implications of screening for the particular condition or pre-disposition and any follow-up arrangements, including counselling and support services, should likewise be discussed with the patient.

## 14 Consent to research

The benefits of medical research may not apply to the individual research participant. Participants should understand this and that the results of research are not predictable. They should receive any information about possible benefits and risks that are known. A properly constituted research ethics committee approval should be made evident to the participants. It should be clearly stated that the participants can withdraw from the research programme at any time and that withdrawal will have no effect upon their subsequent medical care. Express consent in writing is required from the participants. No pressure must be put upon the potential participants to take part in the research activity from the individuals responsible for obtaining consent or from anyone involved in the research project.

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