



# **National standard site-specific radiotherapy consent forms**

## **Development**

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## 1. Purpose of the guidance

The purpose of this guidance is to:

- Describe the context around the requirement for consent for radiotherapy
- Outline the legal changes in taking of consent since 2015
- Demonstrate the rationale and need for national standard site-specific radiotherapy (SSR) consent forms
- Explain the robust process through which the SSR consent forms were designed
- Provide the protocol for development of further forms

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## 2. Radiotherapy and consent

As with all medical and surgical procedures, it is a requirement to take consent for radiotherapy. There is a unique complexity to the consent process for radiotherapy as there are both significant acute risks associated with treatment and late toxicities which may present years after treatment.

It is therefore generally accepted that the best ethical and legal practice is to ensure valid written, signed consent is sought before starting radiotherapy treatment. The taking of written consent should follow a full discussion with the patient of the intended benefits and risks of the treatment. Valid consent is fundamental to respect a patient's autonomy and is a legal requirement.<sup>1</sup>

However signing a consent form is not a substitute for a meaningful dialogue and discussion with the patient about treatment. The General Medical Council (GMC) guidance on decision-making and consent was updated in 2020.<sup>2</sup> It reiterates the importance of shared decision-making and of ensuring a good understanding of each patient's priorities. The patient must be given information on the aims of treatment and side-effects as well as other treatment options, including the risks and benefits of each. This should be supported with contemporaneous documentation in the patient records confirming this process has been completed.

Information should be given in the most considerate way possible with time to reflect before and after decision-making. The GMC states: 'you should not make assumptions about: a) the information a patient might want or need, b) the factors a patient might consider significant, c) the importance a patient might attach to different outcomes.'<sup>2</sup>

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## 3. Radiotherapy and consent update 2015 – Montgomery judgement

There have been several high-profile cases over the last 20 years which have had a significant bearing on consent. Most notably, in 2015 the Montgomery judgement changed the landscape for clinicians.<sup>3</sup> Historically, when assessing whether a doctor had discharged his duty to properly inform a patient of all the relevant information before obtaining consent, the test was the familiar *Bolam* one applicable to professional standards. A doctor only had to demonstrate that he had acted in accordance with a practice supported by a reasonable group of responsible doctors practising in that particular field. A doctor was only required to provide additional information about risks in response to direct questioning. That changed significantly with the decision of the Supreme Court in *Montgomery v Lanarkshire Health Board*.<sup>3</sup> The Court held that:

*'The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable*

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*alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.'*

The Court emphasised the importance of a dialogue with the patient to identify which specific factors would be material. Furthermore, patients should be made aware of any reasonable alternative or variant treatments.

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#### 4. Radiotherapy consent: rationale for development of national standard site- specific radiotherapy consent forms

For some years the RCR have been approached by clinicians asking for a national standard consent form similar to those used for systemic anti-cancer therapy – most notably in the heads of service meetings. Many centres have their own SSR consent documents – 54% have a SSR consent form for prostate cancer – but there is no consensus among these forms in terms of the side-effects that are included.<sup>4</sup> This suggests that there may be inconsistency in consultations with patients regarding the side-effects of radiotherapy.

There are many reasons that a national standard SSR consent form would assist clinicians and patients alike. In an increasingly litigious society, there are obvious advantages to having commonality in consent forms and processes.

1. A reduction in unnecessary and wasteful duplication of work as each hospital will be able to use a pre-existing form rather than developing their own.
2. Reducing the risk of unreliability in obtaining consent that can result from forms and processes in some centres being less robust.
3. Minimising the chances that there will be different consent forms in use in different centres, identifying different risks. In that case the more comprehensive forms may be relied upon in support of claims against centres with less detailed consent forms.
4. Simplifying the training of doctors and radiographers in the obtaining of consent
5. Avoiding any confusion when practitioners (doctors and suitably qualified radiographers) move between centres as consent processes will remain uniform
6. Facilitating peer review to identify and support any practitioners who are practicing in a very different way as standard/expected practice will be clear and uniform
7. The ability to share revisions and improvements based on the experience and feedback of practitioners and/or patients across all centres.

The underlying driver is a desire to provide optimal care to patients. This cannot be achieved unless patients are provided with the treatment options that are relevant to them, together with information about the associated risks and benefits. In this way we protect patient autonomy and provide optimal, patient-centered care.

The RCR has a leading role in providing guidance and professional support to clinical oncologists across the country. Therefore, it is appropriate that the RCR publish a suite of national consent forms.

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## 5. The process for developing SSR consent forms

A national steering group has been set up to oversee the development of SSR consent forms. Members include a patient representative, a lawyer, a radiographer, a nurse clinician and clinical oncology doctors at both specialty training and consultant grade.

The role of the national steering group includes reviewing, amending and approving:

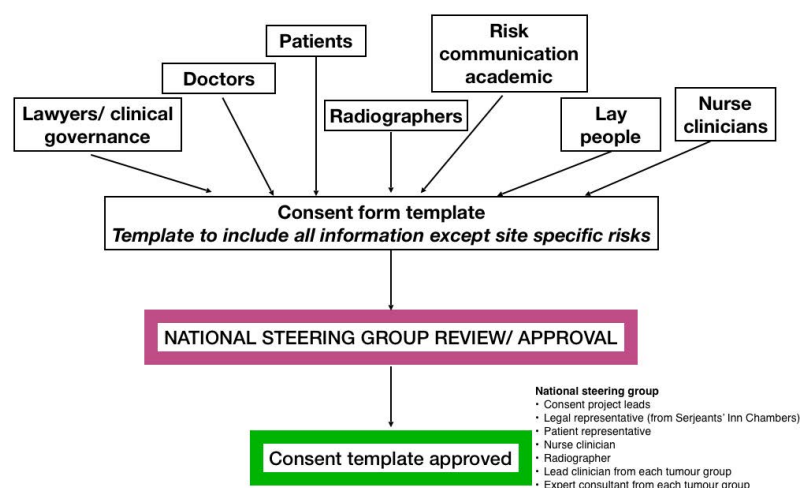
1. The consent form template
2. The protocol for collating the site-specific side-effects to generate the SSR consent forms
3. The process for updating SSR consent forms
4. All completed SSR consent forms prior to publication on the RCR website.

### Development of the national standard consent form template

The consent form template is based on consent form one. The development process had input from risk communication academics from the Winton Centre for Risk and Evidence Communication, University of Cambridge. The consent form template has been reviewed, discussed and amended in focus groups by:

- A legal team from Serjeants' Inn Chambers
- Clinical oncology specialist trainees and consultants
- Radiographers/radiotherapy service managers
- Nurse clinicians
- Patients.

**Figure 1. Developing the national standard consent form template**



The consent form template was reviewed by the RCR heads of service group and the Professional Support and Standards Board. The consent form template was reviewed, amended and approved by the national steering group and can be found on the RCR website .

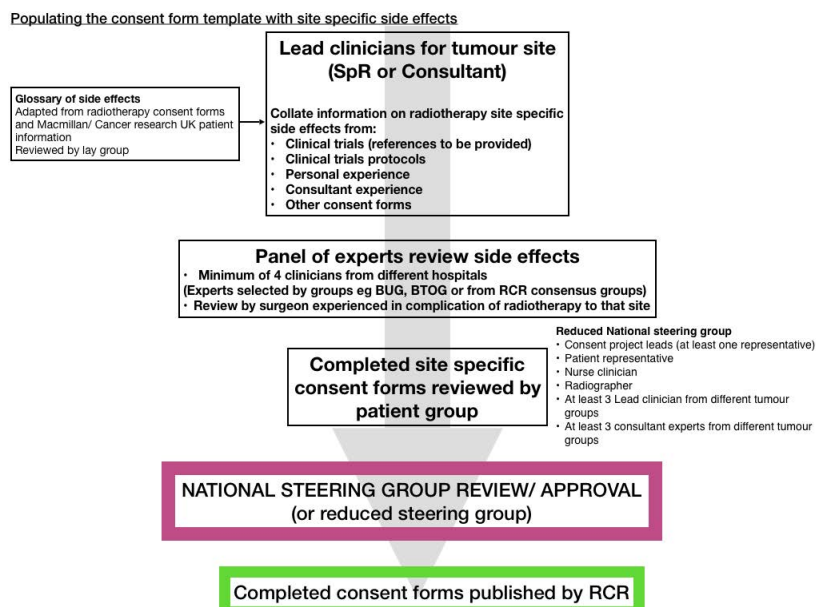
## Process for inclusion of site specific side-effects

For each radiotherapy consent form, site-specific side-effects are collated from:

- Clinical trials
- Clinical trials protocols
- Personal experience
- Consultant experience
- Other consent forms.

The findings from these sources are collated by one or two consultants or clinical oncology specialist trainees for each SSR consent form. Once the side-effects have been added to the template, each SSR consent form is reviewed, amended and approved by a panel of experts in that tumour site (selected from groups such as the UK Breast Cancer Group, the British Uro-oncology Group, the British Thoracic Oncology Group, the British Gynaecological Cancer Society and RCR consensus groups). Each expert panel includes a minimum of four experts from different hospitals. Where appropriate, the side-effects are reviewed by a surgeon who is experienced in dealing with the side-effects of radiotherapy to that area. All completed SSR consent forms are reviewed for clarity by a patient group. The final version of each SSR consent form is reviewed and approved by a reduced national steering group.

**Figure 2. Populating the consent form template with site-specific side-effects**

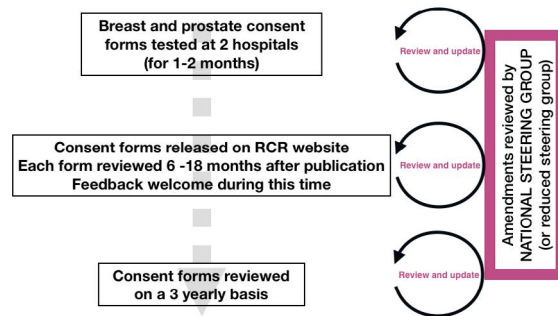


During the initial development of the forms, prostate and breast radiotherapy consent forms were released as a pilot in two hospitals. Based on feedback from the pilots, forms were updated where relevant. Subsequent consent forms will not be piloted.

On completion, SSR consent forms are published on the RCR website and reviewed/ updated according to feedback after six to 18 months. After the first review, SSR consent forms will be reviewed every three years. Major amendments will be approved by the national steering group.

**Figure 3. Review and updating of radiotherapy site-specific consent forms**

Review and updating of radiotherapy site specific consent forms



To facilitate consistency between the SSR consent forms, a glossary of side-effects has been developed. This can be found at [Appendix 1](#).

To cover the most common sites to which radiotherapy is delivered, the process of developing SSR consent forms will be on going over the next few years. Please contact [professionalservices@rcr.ac.uk](mailto:professionalservices@rcr.ac.uk) if you would like further information or advice on this.

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## References

1. Department of Health, Social Services and Public Safety. *Reference guide to consent for examination, treatment or care*. Belfast: Department of Health, Social Services and Public Safety, 2003.
2. General Medical Council. *Guidance on professional standards and ethics for doctors. Decision making and consent*. Manchester: General Medical Council, 2020.
3. *Montgomery (Appellant) v Lanarkshire Health Board (Respondent) (Scotland)* (2015) UKSC 11.
4. Kenney-Herbert E, Mylonas M, Todd J, Tipples K. Consent consensus: time for a national site-specific consent form for radiotherapy? *Clin Oncol (R Coll Radiol)* 2021; **33**(1): 1–4.



## Appendix 1. Glossary

We have developed a glossary of suggested terms to be used for certain side-effects of radiotherapy. This is to facilitate consistency across all RCR SSR consent forms. This is not a complete list of side-effects but does include common side-effects that might be seen on more than one SSR consent form. It should also give an idea of style to the authors of specific forms.

The glossary terms are adapted from hospital radiotherapy consent forms in circulation. The language has been adapted to ensure it matches that used by the Macmillan and Cancer Research UK websites in their patient leaflets.

The glossary has been reviewed and amendments made by a group of lay people.

### General

- Hair loss in treatment area
- Tiredness
- A different cancer in the treatment area – not related to your current cancer, which may occur many years after treatment
- Loss of appetite

### Skin

- Skin soreness, redness and itching in the treatment area
- Skin texture changes in treatment area including – thicker or thinner skin
- Skin colour change in the treatment area – usually lighter or darker
- Telangiectasia in the treatment area – small visible blood vessels which look like spidery marks

### Bone

- More prone to bone fractures in radiotherapy treatment area

### Nerve damage

- Brachial plexopathy – nerve damage which may cause pain, numbness or tingling affecting the arm and shoulder

### Head

- Increased risk of stroke
- Cataract – clouding in the lens of the eye, which may require surgery to correct
- Risk of damage to nerves affecting vision
- Radionecrosis of the brain – damage to a small area of the brain which is not repairable
- Pituitary dysfunction – your pituitary gland not producing enough hormones, this may require you to take medication to replace the hormones

### Ears

- Hearing loss or hearing changes
- Tinnitus (ringing in the ears)

### Mouth/throat

- Redness/swelling/ulceration/pain of the mouth or throat
- Dry mouth
- Thickened and tenacious secretions
- Voice changes
- Trismus – jaw stiffness
- Lymphoedema – skin, chin and soft-tissue swelling
- Hypothyroidism – under-active thyroid gland, which may require you to take medication
- Osteoradionecrosis of the jaw – damage to the jaw-bone

### Oesophagus

- Dry mouth
- Increased saliva or mucous production
- Dry oesophagus
- Inflammation of the oesophagus which may cause pain and/or difficulty with swallowing
- Oesophageal dysmotility causing a change in swallow
- A feeling of food getting stuck in the food pipe
- Indigestion or heartburn
- Feeding via a tube into the stomach/small intestine

### Breast

- Breast swelling
- Breast/chest wall discomfort including aching and shooting pains
- Lymphoedema of the arm (fluid collecting in the arm which may cause swelling, pain and or movement difficulties)
- Subtle changes to breast appearance including change to breast size, shape and texture
- Worsened cosmetic outcome after reconstruction surgery – which may require the implant to be replaced

### Cardiac

- Increased risk of heart attack

### Lung

- Shortness of breath or cough (moderate to severe) which can affect day-to-day life and is caused by pneumonitis (temporary inflammation of the lungs)
- Coughing-up small amounts of blood
- Lung fibrosis – scarring of the lung which can be seen on an X-ray or computed tomography (CT) scan which usually does not cause a significant increase in breathlessness
- More prone to rib fractures in radiotherapy treatment area

### Limbs

- Fibrosis (scarring or thickening of muscle and tissue)
- Joint stiffness
- More prone to bone fractures in radiotherapy treatment area

### Gastrointestinal

- Nausea – feeling sick
- Vomiting

### Urinary problems

- Discomfort
- Frequency: passing urine more often than normal
- Urgency: a sudden urge to pass urine more often than normal
- Slower urinary flow compared to normal
- Cystitis/pain/discomfort when you urinate: due to bladder inflammation
- Urinary leak or incontinence
- Urinary retention – not being able to pass urine or not being able to fully empty your bladder, both of which may result in needing a urinary catheter
- A hole in your bladder or a fistula which may require surgery to repair

### Bowel problems

- Discomfort
- Diarrhoea
- Frequency: opening your bowels more often than normal
- Passing more mucus or wind compared to what is normal for you
- Pain in the abdomen/back passage
- Incontinence: mild/moderate
- Bleeding from the rectum, causing blood in the stool
- Perforation: a hole in your bladder or bowel

### Sexual function

- Infertility – please ask patients about their plans for having children and advise accordingly
- Change in sexual experience including inability to ejaculate, dry ejaculate, erectile dysfunction (difficulty achieving erections or having erections firm enough for penetrative sex)
- Narrowing and dryness of the vagina, which may cause pain and make sexual activity more difficult
- Early menopause

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### Legal team

#### **Serjeants' Inn Chambers**

Michael Mylonas QC

Ronald Davidson

Richard Partridge

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### Risk communication expert

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The Royal College of Radiologists

The Royal College of Radiologists  
63 Lincoln's Inn Fields  
London WC2A 3JW

+44 (0)20 7405 1282

[enquiries@rcr.ac.uk](mailto:enquiries@rcr.ac.uk)

[www.rcr.ac.uk](http://www.rcr.ac.uk)

[@RCRadiologists](https://twitter.com/RCRadiologists)

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