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Clinical Oncology

The Royal College of Radiologists

National standard site-specific radiotherapy consent forms

Implementation

April 2021

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1. Purpose of the guidance

The purpose of this guidance is to:

- Provide guidance for the introduction of site-specific radiotherapy (SSR) consent forms in your hospital
- Provide guidance in relation to obtaining consent for adults who will be undergoing treatment with radiotherapy
- Provide guidance for the use of the SSR consent forms.

2. Guidance for the introduction of site-specific radiotherapy consent forms in your hospital

The process for the introduction and local adoption of SSR consent forms may be different for each radiotherapy provider. The RCR supports and advises that hospitals use the SSR consent forms for radiotherapy. However, the RCR does not mandate the use of these forms.

A request to use the SSR consent forms should be submitted to the clinical governance or consent committee at the individual hospital. This submission can be supported by the national standard consent form summary letter, a template of which is provided in **Appendix 1**.

A standard operating procedure or guideline for use of the SSR consent forms should be developed. This should describe the process for:

- Downloading and printing of the forms from the RCR website, including appropriate version control
- Storage of blank forms
- Giving the patient a copy of completed forms
- Filing of completed forms in each patient's record.

It is important that departments also have a local policy for patients to opt out of the use of information collected during radiotherapy being used in research, audit and teaching.

3. Guidance for the process of taking consent

Doctors should be familiar with the process of taking consent and should follow the General Medical Council (GMC) guidelines as set out in their document *Decision making and consent 2020*.[1]

Who can take consent?

Consent should be taken by a healthcare professional with sufficient training and experience who is also experienced in the management of the radiotherapy treatment site and protocol. It is expected that a competent healthcare professional will be one of the following:

- A consultant clinical oncologist
- A specialist registrar, clinical fellow or staff-grade doctor in clinical oncology who has had training in consent for that radiotherapy treatment plan
- An expert radiographer or specialist nurse with specific training in consent for that site of radiotherapy.

Who can give consent?

Adult patients with capacity can give consent. The RCR SSR consent forms should not be used in situations where a patient lacks capacity. In this situation the hospital should provide an appropriate alternative form. The RCR SSR consent forms should not be used for children/minors who are undergoing radiotherapy.

When should consent be taken?

Consent should be obtained and documented before patients begin their course of radiotherapy . Ideally there should be time (measured in days rather than hours) for the patient to reconsider their decision to undergo treatment before the first fraction is administered. However, we appreciate there are times when this may not be feasible such as when patients have presented with spinal cord compression.

Confirmation of consent

When consent is taken in advance of treatment the patient should be asked to confirm consent before the start of treatment, for example, at their planning appointment. This will be documented on the consent form. Where a patient expresses doubt about proceeding with the treatment, the opportunity to have a second consultation with a suitably trained and experienced healthcare professional prior to commencing treatment should be offered.

Renewed consent should be sought where there is material change in the radiotherapy which will be delivered, which was not discussed at the initial consent. A material change could be a change in the site to be treated or a change in the diagnosis.

A patient can withdraw consent at any time. Where consent is withdrawn this should be discussed and documented in full in the patient notes.

4. Guidance for the use of SSR consent forms

The SSR consent form is designed to be robust and to give the space for clinicians to amend and adapt the form according to the particular patient and their treatment. Some patients may have specific health conditions or jobs or may participate in activities that mean the significance to them of a specific side-effect is different. These should be included in the section of the SSR consent forms labelled 'Specific risks for you from your treatment'.

Additional considerations should be completed by the clinician in cases where, for example, the patient has had previous radiotherapy, is taking medication which may act as a radiosensitizer or if a patient cannot undergo certain procedures such as blood transfusions.

The consent form does not replace the need for a conversation and dialogue around the consent process. In light of the Montgomery judgment it is essential that alternative treatments are discussed with the patient prior to the process of taking consent.[2] Alternative treatments, including no treatment and the surrounding discussions should be documented in the patients notes/records. Discussions should be personalised and must include any specific risks that are likely to be significant to that patient.

While every effort has been made to include side-effects on the SSR consent from which are applicable to each site of radiotherapy it remains the role of the clinician to ensure that the correct side-effects are documented on the consent form, even if this requires significant amendment.

References

1. General Medical Council. *Guidance on professional standards and ethics for doctors. Decision making and consent.* Manchester: General Medical Council, 2020.
2. *Montgomery (Appellant) v Lanarkshire Health Board (Respondent) (Scotland)* (2015) UKSC 11.

Appendix 1. National standard consent form summary letter

Name and address of provider organisation

Date

To: *Chair of governance/consent committee*

Dear *Chair name*

Re: National standard site specific radiotherapy consent forms

The Royal College of Radiologists has issued guidance relating to consent for radiotherapy. It has recommended the use of the national standard consent forms which have been developed following a robust protocol with approval of a national steering group. These consent forms are available on The Royal College of Radiologists' website >>>>>>>>>>>> and are designed to support best practice in consent for radiotherapy.

The *name of radiotherapy group* have considered this recommendation and benchmarked our existing radiotherapy consent practice against the national guidance. Our existing practice is *give a brief description, for example consent form 1*. Following this exercise the group have decided that they wish to adopt and implement use of the national standard site-specific radiotherapy consent forms into local practice for the benefit of our service and ultimately our patients. To support this we have outlined a proposed local process for use of the forms which is enclosed with this submission.

Please consider this a proposal to use the national standard site-specific radiotherapy consent forms in preference to our existing practice.

Yours sincerely,

Chair of radiotherapy group

Enclosed

- Sample SSR form
- Local process for the use of SSR consent forms

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