Western Health and Social Care Trust

Policy for the use of Site Specific Consent Forms for Radiotherapy Treatment

June 2017

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Title:	Policy for the use of Site Specific Consent Forms for Radiotherapy Treatment	
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1. Introduction:

Since 2001, the Department of Health guidance on consent has required NHS Trusts to adopt a model consent policy, model forms and information leaflets with the aim of ensuring good practice in seeking consent throughout the NHS. In Northern Ireland this guidance takes the form of "Good Practice in Consent: Consent for Examination Treatment or Care. A Handbook for the HPSS 2003". Within this guidance there is a capacity for high through-put specialties within Trusts to customise the model documentation to reflect local needs and enhance the consent process. The degree of customisation permitted is clearly stated within the guidance and direct engagement with the DHPSS in developing the site specific radiotherapy consent forms was undertaken by the Radiotherapy Team at Belfast Health and Social Care Trust in 2011.

Since issuing the 2001 guidance the Department of Health continues to recognise that NHS Trusts require up to date, effective guidance to allow them to ensure they have effective and legal consent processes in place. It is currently undertaking a review of Consent in the NHS and as an interim measure has issued new guidance for consent in the form of "Reference Guide to consent for examination or treatment. Second edition 2009". This guidance reflects new legal developments since the 2001 guidance including the Human Tissue Act 2004, the Mental Capacity Act 2005 and relevant judgements made in the High Court of Justice. In order to ensure that NHS trusts continue to have in place effective and legal consent processes whilst this review takes place, the DH, as an interim measure, will permit trusts to develop consent forms based on the DH model to reflect the current legal position and reflect local practice and statutory regulations.

The WHSCT's Employers Procedures for External Beam Radiotherapy as required by the Ionising Radiation (Medical Exposures) Regulations (NI) 2000 (& 2010 Amendment) require IRMER Practitioners to establish pregnancy status of female patients of childbearing age, and to advise the patient of the risks should she become pregnant before or during her course of External Beam Radiotherapy. This should be documented on the patient's signed consent form by the Practitioner, prior to Radiotherapy planning. Where pregnancy status is irrelevant, the Practitioner must document the consent form appropriately. It therefore follows that integration of this legal requirement into the site specific consent form, where appropriate, further enhances the consent process.

2. Purpose:

The use of site specific consent forms ensures a safe, standardised approach to documentation of commonly and less commonly occurring but serious side effects from radiotherapy treatment and appropriate documentation of pregnancy status of female patients of childbearing age. This approach ensures an effective and legal consent process based on the DH model which reflects the current legal position and local statutory regulations including IRMER legislation requirements.

3. The Scope:

This policy applies to all clinical staff employed by the WHSCT involved in consenting of patients for radiotherapy treatments. The site specific consent forms are based on DH model 3 consent form and as such the DHPSS Form 3 “Guidance to Healthcare Professionals” applies. These guidance notes will be clearly displayed in all clinical assessment rooms in the radiotherapy department.

Site specific consent forms will be used for high volume treatment sites only. For treatment sites where site specific consent forms have not been developed the standard DH Form 3 consent form will continue to be used.

NB this policy was developed by the Belfast Health and Social Care Trust in 2011 following liaison with DHSSPSNI. It has been agreed regionally by the Radiotherapy Programme Board that the Radiotherapy Service at Altnagelvin will adopt the same policy when the service goes live in 2016.

4. Objectives:

1. To provide the patient with clear consistent documentation of the treatment intent and potential benefits of radiotherapy treatment.
2. To ensure that all patients are given the same information during the consent process for radiotherapy treatment.
3. To provide the patient with clear consistent documentation of all significant possible side effects of treatment. This includes both frequently occurring and less frequently occurring

but serious side-effects, however small the probability of the risk of these occurring may be.

4. To ensure that pregnancy status is documented on radiotherapy consent forms of all female patients where relevant thereby fulfilling IRMER legislative requirements.
5. To ensure a unified approach to documentation of consent for radiotherapy treatment.
6. To improve documentation of the consent process which can be demonstrated through audit?

5. Roles and Responsibilities:

It is the responsibility of all those involved in the consent of patients for radiotherapy to familiarise themselves with the content of these guidelines and the procedural arrangements detailed in the WHSCT Radiotherapy Service Quality Management System.

Where site specific consent forms have been developed for a specific treatment site/disease group, it is the responsibility of all clinicians, involved in the treatment of this site/disease group, to ensure, in consultation with each other, that all significant possible side effects/adverse outcomes, both frequently occurring and less frequently occurring but serious, however small the probability of the risk occurring have been detailed on the form.

Clinicians & clinical site specialist radiographers are responsible for liaising regionally within each disease site to ensure that site specific consent forms are up-to-date and fit for purpose. The site specific consent forms will be incorporated into the radiotherapy clinical protocol for the disease site for which it relates to. The disease specific group will be responsible for reviewing the site specific consent forms bi-annually as part of the clinical protocol review process under the radiotherapy department quality management system.

It is the responsibility of the clinical lead for each treatment site/disease group to approve/authorise the current version of the site specific consent form and to bring any proposals for change forward for discussion at the appropriate NI Regional Radiotherapy Forum.

6. Supporting Evidence

Radiotherapy is a non-surgical form of cancer treatment which uses high-energy X-rays, electrons or other forms of radiation in the treatment of cancer in both curative and palliative settings.

For the consent to Radiotherapy to be valid it should be given voluntarily, freely and without duress by an appropriately informed person who has the capacity to consent to the examination or treatment. Consent is a process, not a one off event. Patients can change their mind and withdraw consent at any time.

Limits of Customisation of DH Consent Forms:

The DHPSSNI limits of customisation of the department of health consent forms directions are listed below:

- ***"Customisation of model documentation***

  Both consent forms and consent policy should be recognisable across the HPSS and the text included in this implementation guide should not be amended or removed. However, it may be appropriate to customise the documentation to reflect local needs, and the extent to which customisation is acceptable is set out below.

- ***Consent forms – Appendix B***

  Additional material relevant to local circumstances may be included in consent forms, as long as this does not result in forms becoming too unwieldy or in the font size being reduced inappropriately. HPSS trusts who have developed the practice of documenting anaesthetic consent on the main consent form (as opposed to on the anaesthetic record) should feel free to include such a section within their new forms. Relevant sections of the forms (such as those dealing with benefits and risks) may be pre-printed where high through-put specialities make this feasible and desirable. If this is done, it will, of course, always be necessary for health professionals to consider whether additional risk/benefit information should be added by hand, to reflect the particular needs of the individual patient. It is essential, however, to ensure that this does not lead to a 'conveyor belt' approach to consent in these circumstances.

  While consent forms 1 and 2 have been designed in the form of 4 page booklets with the crucial information for patients on the facing inside pages, they may if desired be reduced to 2 sides of a single sheet by making the guidance notes on the back available to health

professionals another way. There must, however, be clear reference on the forms to the availability of these guidance notes, which must be readily accessible. As the guidance notes on consent form 2 (which explain the relatively complicated legal position regarding who may give consent on behalf of a child) may be less familiar to health professionals, it may generally be more appropriate to this this approach for consent form 1 than for consent form 2.

Whatever the format used, a copy of the page documenting the details of the treatment should be offered to the patient, for example through the use of 'no carbon required' (NCR) copies". DH 2003.

Accompanying Information:

Patients should be given site specific information sheets pertaining to potential radiotherapy side effects and will be offered a copy of the signed consent form.

7. Policy/Guideline description:

To support clinicians in the process of consent for site specific radiotherapy treatments.

8. Policy statements:

Clinical staff must be satisfied that the patient has understood the proposed treatment and that the patient is content to proceed with radiotherapy treatment. Clinical staff must ensure that the appropriate site specific consent form has been used. Where no site specific radiotherapy consent form has been developed the appropriate DH model consent form (1,2, 3 or 4) should be used.

9. Implementation/Resource requirements

These guidelines will be implemented by all staff involved in gaining consent for radiotherapy treatments.

10. Source(s)/Evidence Base:

BHSCT – Policy for use of site specific consent forms for Radiotherapy Treatment 2011.

11. Equality and Human Rights screening carried out:

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998) Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, the Western Trust have carried out an initial screening exercise to ascertain if this policy should be subject to a full impact assessment.

[x]	Screening completed. No action required.	[ ]	ull impact assessment to be carried out

12. Review Date

WHSCT review date – October 2017.
In the future, this will move to become a regional policy in conjunction with BHSCT.