Consent forms for Systemic Anti-Cancer Therapy (SACT)

Frequently Asked Questions (FAQs)

Which tumour site groups are forms available for?
The regimen-specific forms are being published in tumour site groups, on a rolling schedule. The order of roll-out is as follows:

Tumour site	Publication date
Generic consent form	Jul-16
Breast	Jul-16
Head & Neck	Oct-16
Skin - Melanoma	Nov-16
Immunotherapies generic form	Dec-16
Gynaecology	Jan-17
Lung	Mar-17
Colorectal	May-17
Supportive meds	Apr-17
Urology-bladder	Jul-17
Thyroid	Sep-17
Upper GI - OG & GIST	Oct-17
Upper GI - HPB	Dec-17
Urology - Prostate	Dec-17
Urology - Germ cell	Apr-18
Haematology CML	May-18
Brain & CNS	
Upper GI - Neuroendocrine	
Urology - Renal cell (9) & Small cell (2)	
Skin - Non-Melanoma	
Myeloproliferative neoplasms (MPN)	
Chronic lymphocytic leukaemia (CLL)	
Multiple Myeloma	
Lymphoma	
Acute myeloid leukaemia (AML)	
Acute lymphoblastic leukaemia (ALL)	

Please check the website regularly (e.g. once a month) for new forms and updates.

What should I do if I cannot find the regimen-specific form I need?
We would encourage Trusts to us the generic form where a regimen-specific form does not exist.

When will the consent forms for the haematology tumour groups be available?
CML consent forms have now been published. The other haematology sub-groups will follow.

What should I do if I am experiencing problems accessing the forms on the website?
If you can't open the accordions or download the forms, it's usually because of the browser or the computer settings. If it's the browser, it's often due to a corrupt or long session, so closing the browser and opening a new one and trying again should fix it. If not, try re-booting to clear the memory and trying again. If you're still experiencing problems contact your IT team to check your settings aren't preventing downloads. The forms are PDFs so you will need Adobe Acrobat to read them. If you don't have this, you should be prompted to download it when you try to open a form. Check with your IT team if you have problems viewing the downloaded forms.

How have the forms been developed and what is the governance process?
The forms are based on the Department of Health consent form 1. The template form has been approved by the UK Chemotherapy Board. Each hospital/Trust will need to ensure that the forms are approved for use locally by their governance or consent committee, whichever is most appropriate for the individual organisation. Please refer to the "Guidance on consent for SACT" on this website.

The consent forms and the legal process.
The consent form is not a legal document but it represents best practice and conforms with and complements the guidance documents available to clinicians taking consent. Several guidance documents have described best practice in the area of consent with respect to law, ethics, training and experience required and the need for documentation that consent has taken place.

We explored informal counsel with a medico-legal advisor, in response to the issue of the Montgomery judgement. The following has been taken from their reply:

> *"The issue of Montgomery is much misunderstood I think in terms of what it means for individual clinicians. It does have a bearing on the legal position if a claim is made, but the standard to which individual doctor must adhere with regard to the consent process is the GMC guidance.*
> *The Montgomery judgement really only brings the legal situation in the claims process into line with what doctors have been obliged to do since this GMC guidance was issued in 2008.*
> *The most important aspect of the GMC guidance is that information about risk must be individualised for that patient. So for example, risk of cardiac events may be higher in a patient with pre-existing cardiac disease, or peripheral neuropathy may be more relevant if you are a concert pianist, as opposed to a patient who is not.*
> *These are probably the most comprehensive and patient friendly consent forms I have seen."*

The consent forms are developed to ensure a high level of consistency in the information giving and discussion with the patient. Your Trust Governance and/or consent committee must agree before you use these forms.

How do I give a copy of the completed form to the patient?
The patient can be given a photocopy of the completed form. We recommend retaining the original form in the patient's records, or a scanned copy in the patient's electronic records.

Would it be possible to add information on extravasation to all intravenous cytotoxic therapies?
In response to a survey conducted across Lead cancer clinicians England and UKONs members, we will be incorporating information as to the risk of extravasation in all intravenous chemotherapy regimens (vesicants, irritants and neutrals). This will not apply to immunotherapy drugs.

Are there plans for the forms to be made available in Welsh?
We are liaising with NHS colleagues in Wales regards translation of the forms into the Welsh. We plan to translate the generic consent forms. Please check the website for these forms and updates.

Are there any plans to develop chemo-radiotherapy consent forms?
These forms are designed specifically for taking consent for SACT. For instances where the SACT is given in combination with radiotherapy, the radiation therapy will need to be consented for separately. We do not currently plan to develop chemo-radiotherapy consent forms.

Are there plans for the forms to be made available for paediatrics, sarcoma and TYA groups?
We plan to develop national SACT regimen-specific consent forms for these patient groups.

Are there plans for the forms to be made available electronically?
We are currently exploring the feasibility of editable electronic consent forms with Cancer Research UK.

Where can I find more information about the regimen-specific consent forms?
Further information can be found on www.cruk.org/sact_consent.
You can also email rena.chauhan@gstt.nhs.uk or victoria.fashina@gstt.nhs.uk if you have any queries and with any comments.

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