Systemic Anti-Cancer Therapy (SACT) Consent Forms

Frequently Asked Questions (FAQs)

Contents

1. Which consent form groups are available and when will they be reviewed? 2

2. What happens when a new regimen is commissioned before the consent form group is due to be revalidated? 3

3. What should I do if I cannot find the regimen-specific form that I need? 3

4. When will consent forms for the haematology groups be available? 3

5. How have the forms been developed and what is the governance process? ... 3

6. Are the consent forms a legal document? 4

7. How do I give a copy of the completed form to the patient? 4

8. Will the consent forms be made available electronically? 4

9. Can I use the CRUK consent forms, branding and footer on our local electronic consent system? 5

10. Will the consent forms be made available in Welsh and/or other languages? 6

11. Will chemo-radiotherapy consent forms be developed? 6

12. Do you have children and young people (CYP) SACT consent forms? 6

13. Where can I find more information about the regimen-specific consent forms? 7

1. Which consent form groups are available and when will they be reviewed?

The regimen-specific forms have been published for the following tumour site groups.

Each group of forms will be reviewed on a rolling schedule every three years. The process by which each group of forms is revalidated may result in the republication dates exceeding the date of review indicated on each group of forms. All forms are valid until new versions are made available.

Consent Form Group	Issue Date	Review Date
Advanced Systemic Mastocytosis (AdvSM)	Jun 25	Jun 28
Acute Lymphoblastic Leukaemia (ALL)	Mar-24	Mar-27
Acute Myeloid Leukaemia (AML)	Mar-25	Mar-28
Brain & CNS	Oct-26	Oct-29
Breast	June-25	June-28
Children & Young Person ALL	Aug-23	Aug-26
Children & Young Person Generic	Sep-22	Sep-25
Chronic Lymphocytic Leukaemia (CLL)	Nov-23	Nov-26
Chronic Myeloid Leukaemia (CML)	Jul-23	Jul-26
Colorectal	May-26	May-29
Gastrointestinal Stromal Tumour (GIST)	Jul-23	Jul-26
Generic English SACT & Immunotherapy	Nov-23	Nov-26
Generic Welsh SACT & Immunotherapy	Nov-23	Nov-26
Gynaecological	Nov-24	Nov-27
Head & Neck	Oct-26	Oct-29
Hepatobiliary	Sept-24	Sept-27
Kaposi Sarcoma	Jul-23	Jul-26
Lung	June-26	June-29
Lymphoma	Nov-25	Nov-28
Lymphoma (Phase 2)		In development
Multiple Myeloma (Phase 1)	Sept-24	Sept-27
Multiple Myeloma (Phase 2)		In development
Myeloproliferative Neoplasms (MPN)	Oct-24	Oct-27
Neuroendocrine & Adrenal	May-24	May-27
Oesophagogastric	May-25	May-28
Sarcoma	Mar-24	Mar-27
Skin – Melanoma	Mar-25	Mar-28

Skin – Non-Melanoma	Feb-24	Feb-27
Supportive Medicines	Aug-25	Aug-28
Thyroid	Aug-25	Aug-28
Urology – Bladder	Jan-25	Jan-28
Urology – Germ Cell	June-24	June-27
Urology – Prostate	Mar-26	Mar-29
Urology – Renal Cell Carcinoma	Mar-26	Mar-29
Urology – Small Cell	Mar-26	Mar-29

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

2. What happens when a new regimen is commissioned before the consent form group is due to be revalidated?

We are working to develop and publish consent forms in time with publication of positive NICE (England), AWMSG (Wales), SMC (Scotland) and HSCNI (Northern Ireland) determinations.

3. What should I do if I cannot find the regimen-specific form that I need?

We encourage Trusts to use the generic SACT or immunotherapy forms where a regimen-specific form is not available. Please get in touch with the project lead pharmacist so that this can be discussed with the tumour-specific lead consultant for development. Contact details for the project lead pharmacist are found at the end of this document.

4. When will consent forms for the haematology groups be available?

CML, CLL, MPN, AML, ALL and multiple myeloma consent forms have now been published. Lymphoma consent forms are in development.

5. 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 Systemic Anti-Cancer Therapy 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 available on this website.

6. Are the consent forms a legal document?

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.

7. How do I give a copy of the completed form to the patient?

The patient can be given a photocopy or print out of the completed form. For trusts using electronic consent systems, there may be different mechanisms for providing the patient with a completed form depending on the system used, such as through secure email or a mobile application. We recommend retaining the original form in the patient's records, or a scanned copy in the patient's electronic records.

8. Will the consent forms be made available electronically?

Due to the complexity of the IT infrastructure, numerous electronic patient records and SACT prescription systems across the NHS, the project team cannot provide one single national electronic consent solution.

An electronic consent working group was subsequently formed as part of the project. The working group developed and published the 'Guidance for the Implementation of CRUK SACT Consent Forms Electronically'. It is intended for use by NHS SACT providers wishing introduce electronic consent to decide which electronic consent solution would be the most appropriate for their individual needs. Guidance for the configuration and maintenance of electronic consent forms, including adoption of the CRUK consent forms electronically, is provided in this document.

9. Can I use the CRUK consent forms, branding and footer on our local electronic consent system?

The CRUK regimen-specific consent forms may be used within local electronic consent systems. As the forms have been through a robust governance process to ensure their consistency and quality, the following disclaimers should be used depending on the applicable scenario. The following disclaimers will be included in the next version of the Guidance on Electronic Consent along with CRUK brand guidelines for logo use.

Use of the consent forms without amendments:

The CRUK logo and consent form footer can be included in electronic consent forms where the content of the forms is used unamended in its entirety. The format, font or colours can be changed if necessary, but the text and CRUK logo should be unamended. The footer at the bottom of each page of the consent form includes the names of those who have prepared, checked and approved the forms, as well as the details of version and date.

In this instance, please include the following disclaimer:

> **The content of this form was developed by Cancer Research UK and Guy's and St Thomas' NHS Foundation Trust. Cancer Research UK and Guy's and St Thomas' NHS Foundation Trust will not accept any responsibility for any claim whether for damages or otherwise, or any other liability arising out of or in connection with the form or its use.**

When amendments are made to the consent form contents:

Where providers base their electronic consent forms on the CRUK consent forms but change some of the content for technical or clinical reasons, the CRUK logo and consent form footer should not be used.

The following disclaimer should be included within the e-consent system in a way that makes it clearly visible to both clinician and patient.

Parts of this form are based on content developed by Cancer Research UK and Guy's and St. Thomas' NHS Foundation Trust. Some of that content may have been selected and/or modified by the electronic system provider, hospital trust or clinician depending on the patient's individual circumstances. It is the responsibility of each individual organisation to ensure that relevant legal requirements and appropriate governance and safety clearance procedures within their own clinical services have been followed prior to implementation of electronic consent. Cancer Research UK and Guy's and St. Thomas' NHS Foundation Trust will not accept any responsibility for any claim whether for damages or otherwise, or any other liability arising out of or in connection with the form or its use.

10. Will the consent forms be made available in Welsh and/or other languages?

The generic SACT and generic immunotherapy consent forms have been translated to Welsh. It is recommended that these forms are used to supplement the English regimen-specific consent forms when a Welsh language accompaniment is required. The project team continues to investigate avenues through which the translation of consent forms can be achieved.

11. Will chemo-radiotherapy consent forms be developed?

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.

The Royal College of Radiologists (RCR) have developed national site-specific radiotherapy consent forms. These can be found here.

The RCR plan to develop chemo-radiotherapy consent forms, but this is an ongoing piece of work for which timelines have not yet been confirmed.

12. Do you have children and young people (CYP) SACT consent forms?

The Children and Young People Generic Form was published in 2021. The ALL in Children and Young People form was subsequently published in 2023. We subsequently plan to develop national SACT regimen-specific consent forms for TYA groups.

13. 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 alia.nizam@gstt.nhs.uk if you have any queries and with any comments.