Consent for Systemic Anti-Cancer Therapy (SACT)

Guidance issued by the UK Systemic Anti-Cancer Therapy Board
June 2024, Version 2

Supported by:

Contents

1.0 Introduction

1.1 Purpose of the Guidance

The purpose of this guidance is to:

- Describe the context relating to the requirement of consent for the administration of systemic anti-cancer therapy (SACT) and outline relevant recommendations from national reports
- Introduce and recommend the use of SACT regimen-specific consent forms for all adults, children and young people, and launch the national library of forms
- Provide guidance for all SACT providers in relation to the local adoption and implementation of national SACT regimen-specific consent forms
- Outline guidance relating to the process of providing information and obtaining consent from adults for treatment with SACT
- Make recommendations for the audit of consent procedures

1.2 Systemic Anti-Cancer Therapy (SACT) and Consent

The use of systemic anti-cancer therapy (SACT) is increasing year on year, and the types of agents are growing. Various new forms of treatment now available which may complement or replace conventional cytotoxic chemotherapy. Treatment with SACT is associated with complex risks with respect to administration and toxicity. Additionally, the risks and benefits of receiving these treatments will differ from patient to patient and, at times, this balance of risk, with respect to toxicity, will need to be carefully considered alongside any potential benefit in terms of survival or symptom control. Because of these issues, the procedure for consent for receipt of SACT involves almost unique uncertainties, and the process of obtaining consent requires considerable expertise and carries specific responsibilities.

Although written consent is not required in law, it is generally accepted that the prescription of SACT is best supported by written consent following a full discussion of the intended benefits and the associated risks. The signing of a consent form indicates that a process has taken place. It does not, necessarily, indicate that the patient has full comprehension of the treatment procedures, aims and complications. Completion of a consent form must, therefore, be complemented by contemporaneous records within the patient notes of discussions which have been held.

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[1-3]. Following the Montgomery case in 2015, the law now requires a healthcare professional to take ‘reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments’[4]. Renewed procedural guidance, based on these existing guidance documents, recent UK case law, and current perceived best practice is given in section 4 of this guidance.

1.3 National Report Recommendations

The National Chemotherapy Advisory Group (NCAG) published its report 'Chemotherapy Services in England: Ensuring quality and safety' in August 2009[5]. The NCAG report was produced to address the significant concerns raised regarding the safety and quality of chemotherapy services in England in the 2008 National Confidential Enquiry into Patient Outcomes and Death (NCEPOD)[6] and cancer peer review reports 2004-2007[7]. The NCAG report made recommendations relating to the whole of the SACT pathway, from referral to an oncologist through to the end of treatment.

The **main proposed actions within the NCAG report in relation to consent and information** were that:

- 'Standardised consent forms are used which include details of the toxicities discussed and which identify whether a patient has been provided with written information.'
- 'A copy of the consent form should be given to the patient as well as one being filed in the patient's case record.'
- 'Standardised written information and other forms of information are given to patients, which are relevant to a particular SACT regimen.'
- SACT service providers should 'provide written information to patients about the SACT they will be receiving, the likely side effects and whom they should contact if problems arise (including out of hours). Delivery of such information should be documented.'

The report recommended that 'consent should be obtained and recorded in detail in terms of the aims of treatment and both the common and serious side effects of treatment'. It also recommended that the quality of assessment and decision making should be assessed through audits of consent procedures coupled with patient experience surveys.

Consent is covered in some degree as part of the National Cancer Peer Review Programme in the Manual for Cancer Services: Chemotherapy Measures[8]. There is a specific measure relating to the consent form (14-3S-132) and checks prior to the prescription of the first cycle of SACT (14-3S-127).

1.4 SACT Consent Forms: Current Status

The Department of Health and Social Care (DHSC) published guidance and four standard consent forms for use in the NHS in 2001. Although DHSC Consent Form 1 is appropriate for interventions where consciousness is not impaired, it lacks the structure to provide the detail that most cancer clinicians and ethicists would consider adequate to support and document the process of consent for SACT. The DHSC guidance was updated in 2009[1] but the gap between the available forms and the requirements for SACT remains.

Because of the limitations of the standard forms available, practice varies widely around the UK. Some SACT providers use or adapt generic DHSC consent forms whilst others have developed more specific documentation that differ in content and style.

2. National SACT Regimen-Specific Consent Forms

2.1 UK Systemic Anti-Cancer Therapy Board Recommendations

The UK Systemic Anti-Cancer Therapy Board recommends the use of standardised SACT regimen-specific consent forms in the UK. This will support SACT providers to adhere to best practice guidance, and address the recommendations and proposed actions in the NCAG report that are relevant to consent. Introduction and adoption of the national forms by all SACT providers will confer the governance and quality benefits of standardised regimen-specific forms to all eligible patients.

SACT regimen-specific consent forms were developed as part of a project funded by the now disbanded South East London Cancer Network (SELCN). This library of forms has been maintained and updated by Guy's and St. Thomas' NHS Foundation Trust (GSTFT) oncology pharmacists and clinicians since 2010. There are over 200 forms available and in use within South East London. Since 2016, this resource, supported by funding from Cancer Research UK (CRUK), has been used to develop and launch the **national library of standardised SACT regimen-specific consent forms which are available to all SACT providers in the UK via the Cancer Research UK website (cruk.org)**.

The national SACT regimen-specific forms include a minimum set of data that is necessary for patient information and fields to be completed to support the process. This also facilitates identification of the completion of responsibilities within the process. It is recognised that some organisations have specific requirements within their own consent procedures that may be outside the content of the forms recommended. Those organisations will be free to augment the recommended national forms; however, it is not envisaged that any content should be deleted locally. In 2023, the format for the consent forms was updated to improve accessibility. See Appendix 1 for an example of a regimen-specific consent form in the updated format and Appendix 2 for an example of a regimen-specific consent form in the previous format.

2.2 Routine SACT Regimens

National SACT regimen-specific consent forms will be made available for all oncology and haemato-oncology regimens that are in routine use within the UK for the treatment of adult, children and young people with cancer. Generic SACT and immunotherapy consent forms are available for adult patients, and a generic SACT consent form is available for children and young people. These forms may be used as an interim measure until all national forms are published.

2.3 Clinical Trials

Many patients with cancer are treated within the setting of a clinical trial. Where SACT treatment is within a clinical trial, the consent for systemic therapy is no different and should follow this guidance.

Trial consent forms do not always contain specific details of the SACT regimen. Where this is the case, separate written consent should be obtained for participation in the trial and then either an existing regimen-specific or the generic regimen-specific form used for consent for the receipt of SACT. This duplication of consent is already embedded in practice in many organisations.

2.4 Chemo-Radiation

These forms are designed specifically for the taking of consent for SACT. For instances where the SACT is given in combination with radiotherapy, the radiation therapy will need to be consented for separately. Consent forms for this purpose are published by the Royal College of Radiologists and available on their webpage (rcr.ac.uk/clinical-oncology/service-delivery/national-radiotherapy-consent-forms).

3. Guidance for the Introduction of the National SACT Regimen-Specific Consent Forms by Individual SACT Providers

The process for the introduction and local adoption of national SACT regimen-specific consent forms may differ for every SACT provider. Key aspects for each provider to consider in relation to the local introduction of the forms are described below.

3.1 Local SACT Group

This guidance document and the national regimen-specific consent forms should be tabled for discussion by the local SACT group, or equivalent. The group should benchmark their current SACT consent processes against this guidance. There should be consensus agreement to work in line with the guidance and adopt the use of the national forms, wherever possible. Ideally, they should nominate a lead person from their membership to take ownership for the introduction of the forms into local practice. They should develop and implement a process for the local use of the forms, to ensure appropriate adoption and observance of clinical governance, described in section 3.3 of this document.

3.2 Governance/Consent Committee

A request to use the regimen-specific SACT forms should be submitted to the SACT provider's governance or consent committee, whichever is most appropriate to approach for the individual organisation. This submission can be supported by the SACT consent summary letter, a template for which is provided in Appendix 3, a copy of this guidance document and an example SACT regimen-specific consent form. The local process for the use of the forms could be sent with other supporting documentation, if this is available at the time of submission.

3.3 Local Process for Use of the Forms

A standard operating procedure (SOP) or guideline for use of the regimen-specific consent forms should be developed. This should describe the process for:

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

4.0 Guidance for the Process of Consent for SACT: Clinical Use and Completion of SACT Regimen-Specific Consent Forms

4.1 Definition of Consent

Consent to treatment is the principle that a person must give their permission before they receive any type of examination or medical treatment. For consent to be valid it must be voluntary and informed and the person providing their consent must have the capacity to make the decision. As described in Section 1.3 of this guidance, although written consent is not required in law, it is generally accepted that the prescription of SACT is best supported by written consent following a full discussion of the intended benefits and the associated risks.

4.2 Who Can Take Consent?

Consent should be obtained by a healthcare professional with sufficient training and experience who is also experienced in the management of the specific SACT regimen for which the patient will consent. The health professional must be aware of their legal, ethical and professional responsibilities with regards to consent, in addition to local institution policies and procedures.

It is expected that a competent healthcare professional will be one of the following:

- A consultant or associate specialist medical or clinical oncologist
- A consultant or associate specialist clinical haematologist
- A specialist registrar, clinical fellow or staff grade doctor in oncology or haematology who has had specific training in consent for systemic therapy
- A non-oncology or non-haematology consultant or associate specialist consultant with specific training and documentation of training to prescribe and consent to SACT in their area of practice
- A nurse, pharmacist or allied health professional prescriber with specific training and documentation of training to prescribe and consent to SACT in their area of practice
- The specific training and proven competency required should be agreed and signed off by the local trust or health board.

4.3 Who Can Give Consent?

This document does not seek to duplicate guidance given elsewhere, i.e. in the DHSC 2009 guidance[1], and its scope does not cover situations where the ability to give informed consent is lacking due to impaired understanding or consciousness. Guidance on this is summarised in the British Committee for Standards in Haematology (BCSH) guidelines on consent 2012[3] and those guidelines should be considered in conjunction with the principles within this document.

4.4 Consent in Children and Young People (Aged 0 – 16 Years)

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. It is good practice to involve those with parental responsibility in the consent discussions, unless the young person specifically asks you not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Children and young people under the age of 16 should be given the opportunity to ‘assent’ to treatment if they wish.

If a young person lacks capacity to give consent as defined in the Mental Capacity Act, then a separate form is available for this purpose.

Due to the rarity and number of different cancers seen in the 0 – 16 years age group, 'regimen-specific' consent forms have not yet been developed, except for Acute Lymphoblastic Leukaemia/Lymphoma (ALL). A 'generic' consent form for children and young people (aged 0 – 24 years) is available on the consent form webpage in addition to the ALL-specific SACT consent form.

4.5 When and Where Should Consent for SACT be Taken?

Consent should be obtained and documented prior to the first cycle of a course of SACT using a defined number of cycles of the same regimen or a defined standard sequential treatment comprising defined numbers of cycles of more than one regimen.

Ideally there should be time (measured in days rather than hours) for the patient to reconsider their decision to undergo the treatment before the first cycle is commenced. It is acknowledged that within many cancer pathways, considerable discussion may have been held between a patient and their key worker or other healthcare professionals prior to a first consultation with a prescriber of SACT, however, full explanation of risks and benefits must still be undertaken during this consultation.

Consent should be taken within a consultation in which:

- The patient (and/or representative) has been introduced to the person taking consent and understands who they are
- The person taking consent can demonstrate that they have sufficient knowledge of the patient's individual circumstances (in particular, co-morbidities) and details of their cancer (usually through a structured consultation and discussion of surgery and/or test results).
- There is sufficient privacy to discuss any issues that may arise
- Any examinations have been undertaken with respect to dignity
- The patient has had the opportunity to involve a relative, friend and/or carer
- The patient has been able to request the presence of their key worker as defined in the Manual of Cancer Services
- The patient and/or relative/friend/carer has had an opportunity to ask any questions that they may have

Where English is not the first language of the patient translation facilities must be available to support the giving of information, answering of questions and taking of consent. It is advised that this should be through a professional translation service in preference to family or friends, other than in exceptional circumstances.

4.6 How Should Consent for SACT be Obtained and Documented?

The SACT regimen-specific form should be used as an aid to the discussions about treatment with SACT. Discussions should be supported by information leaflets for the specific regimen or constituent medicines, e.g. Cancer Research UK or Macmillan information sheets. **The risks and benefits of the treatment, including response rates and alternative or variant options, should be discussed with the patient in terms that they can understand.**

Key aspects of the discussion, which should be documented on the completed form are:

- The aims and intent of the treatment
- The regimen and constituent medicines
- The route of administration
- What the treatment is likely to involve:
  - The schedule of administration and intended duration of treatment with the specific SACT regimen
  - The location of administration (e.g. day-case unit)
  - Description of blood tests and additional tests (e.g. CT scan) and procedures (e.g. PICC line)
  - Outpatient and follow-up appointments
- Short and long-term toxicities, and details of how these may be managed
- The common side-effects and life-threatening complications, even where these are rare
  - The healthcare professional must consider any co-morbidities the patient may have, and how these might impact any relevant toxicities
- Effects on fertility, where relevant, must be discussed
- The form must allow the consenting professional to confirm that advice on avoidance of pregnancy and conception has been provided where relevant
- How and when to contact the hospital team if the patient has any problems or queries regarding their treatment

The consenting healthcare professional must sign the form confirming that the discussions have taken place and that the patient has no further questions and wishes to proceed with treatment. They must ensure that all relevant sections of the form have been completed.

The interpreter should sign the form, where appropriate, confirming that they have interpreted the information to the patient to the best of their ability and in a way which they believe the patient can understand.

The patient should sign the form, once they have confirmed that they wish to proceed with treatment.

A copy of the completed form should be given to the patient with other appropriate information leaflets. The original signed consent form should be filed in the patient records.

4.7 Second Consultations and Confirmation of Consent

The Manual of Cancer Services recommends that all patients should have the opportunity for a routine second consultation with a suitably trained and experienced healthcare professional prior to commencing treatment[8] to ensure that they understand:

- Why the treatment has been offered
- What alternatives could be offered
- What the treatment involves
- What the risks might be
- What the likely benefits might be
- That they can withdraw consent at any time

The requirement for efficient delivery of cancer treatments and the need for urgent therapy should not be limited by the need for this second routine consultation. Hence, the second routine consultation can be performed by a competent SACT nurse (or equivalent) prior to administration of the first cycle of SACT.

Consent must be confirmed and documented on the consent form prior to the administration of the first cycle of SACT where the patient has signed the form in advance, i.e. most instances. This can be done by the treating nurse on the day of treatment. It is good practice to ensure ongoing consent throughout the planned course of treatment, although documentation on the specific form should only be required prior to the first cycle.

5.0 Audit of Consent Procedures

Periodic audit of consent procedures for SACT are recommended. As a minimum, the audit should include the following standards where 100% compliance should be seen:

- Consent forms are available for review
- The name and job title of the responsible healthcare professional are documented
- The treatment intent and intended benefits are documented
- The common toxicities of the SACT are recorded
- The form has been signed and dated by the healthcare professional and the patient

6.0 Acknowledgements, Consultation and Support

This guidance document was initially developed by a working group of the National Chemotherapy Implementation Group (NCIG), which was dissolved in 2012 with the reorganisation of the Department of Health and Social care and the creation of NHS England. The UK Systemic Anti-Cancer Therapy Board acknowledges the work that was done by our predecessors in developing this guidance.

The content of this guidance document has been reviewed and ratified by the UK Systemic Anti-Cancer Therapy Board which has representation from the following National bodies:

- The Association of Cancer Physicians (ACP)
- The Royal College of Radiologists (RCR)
- The Royal College of Physicians (RCP)
- The Royal College of Pathologists (RCPath)
- The UK Oncology Nursing Society (UKONS)
- The British Oncology Pharmacy Association (BOPA)

All representatives have had opportunity to comment and make suggestions on the content of the document and the template regimen-specific consent form.

Cancer Research UK has awarded a grant to Guy's and St. Thomas' NHS Foundation Trust to host and deliver the National SACT regimen-specific consent form project. They are supporting production and hosting of the forms on the CRUK website.

7.0 References and Bibliography

1. *Reference guide to consent for examination or treatment*, Department of Health and Social Care, 2009.
2. *Consent: patients and doctors making decisions together*, General Medical Council, 2012.
3. *Guidelines on Obtaining Consent for Systemic Anti-Cancer Therapy in Adults*, British Committee for Standards in Haematology (BCSH), July 2012.
4. Sokol D. Update on the UK law on consent. *BMJ* 2015; 350:h1481.
5. *Chemotherapy Services in England: Ensuring quality and safety*, National Chemotherapy Advisory Group, 21 August 2009.
6. *For better, or worse?* National Confidential Enquiry into Patient Outcome and Death, November 2008.
7. *National Cancer Peer Review Programme 2004-2007, Overview of the findings from the second national round of peer reviews of cancer services in England,* National Cancer Action Team, June 2008.
8. *Manual for cancer services, Chemotherapy measures, Version 1*, National Peer Review Programme, NHS England, April 2014.

8.0 Appendices

Appendix 1. Example of a national SACT regimen-specific consent form (updated format): Carboplatin-Paclitaxel regimen for treatment of non-small cell lung cancer (NSCLC)

Patient agreement to systemic anti-cancer therapy (SACT)

Carboplatin - Paclitaxel

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ Carboplatin and Paclitaxel chemotherapy for the treatment of non-small cell lung cancer (NSCLC) / thymoma* (*delete as appropriate).

☐ Given intravenously on day 1, every 21 days for 4 to 6 cycles OR

☐ Carboplatin and Paclitaxel given intravenously. Carboplatin on day 1, and paclitaxel on day 1, 8 and 15, every 28 days for up to 6 cycles.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Curative – to give you the best possible chance of being cured.

☐ Disease control or palliative – the aim is not to cure, but to control or shrink the disease and improve both quality of life and survival.

☐ Adjuvant – therapy given after surgery or radiotherapy to reduce the risk of the cancer coming back.

☐ Neo-adjuvant – therapy given before surgery or radiotherapy to shrink the cancer, allow treatment and reduce the risk of the cancer coming back

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – it is harder to fight infections and you can become very ill.
- ☐ If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Thinning of the hair or hair loss, tiredness and feeling weak (fatigue), feeling sick (nausea) and/or being sick (vomiting), watery or sore eyes, sore mouth and ulcers, abdominal (tummy) pain, diarrhoea, muscle and joint aches and pain which may be severe.
- ☐ Numbness or tingling in the hands and feet which may be temporary or permanent, low blood pressure during treatment, and fluid retention (you may notice weight gain and/or your ankles and legs swell).
- ☐ Paclitaxel may cause an allergic reaction while being given. You will have medicines before your treatment to help prevent this.
- ☐ Anaemia (due to low red blood cells), bruising or bleeding (due to low platelets), low electrolyte levels (sodium, potassium, calcium, magnesium), changes in kidney and liver function tests.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Ear problems (changes in hearing and uncommonly high frequency hearing loss which may be permanent, ringing in the ears), eye problems (change in vision), nose bleed, loss of appetite, change in taste, low heart rate, constipation.
- ☐ Sore hands and feet (some people, develop soreness, redness and peeling), skin rash and/or itching of the skin, nail changes.
- ☐ Pain, redness and swelling at the site of the injection.
- ☐ Allergic reactions whilst having carboplatin are not common.

Other risks:

- ☐ All intravenous drugs may leak outside of the vein and damage the tissue around while being given (extravasation). Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein as, extravasation although uncommon, it's important that this is dealt with quickly.
- ☐ Occasionally hair loss may be permanent and nail loss temporary.
- ☐ Changes in the lung tissue may lead to cough, chest pain or breathlessness during or developing in the future. Let your doctor or nurse know if you have these symptoms while at rest or gentle activity.
- ☐ Paclitaxel contains alcohol. This may affect your ability to drive or operate machinery. If this is a problem tell your doctor, nurse or pharmacist.
- ☐ Potential side-effects with the anti-sickness medication may include: constipation, headaches, indigestion, difficulty sleeping and agitation.
- ☐ Steroids and some treatments for cancer can raise your blood sugar. This usually goes back to normal after your treatment. If you have diabetes, it may lead to higher blood sugar levels. Please ask your team/GP if concerned.
- ☐ Cancer and treatment for cancer can increase your risk of developing a blood clot (thrombosis). A blood clot may cause pain, redness and swelling in a leg, breathlessness, chest pain or a stroke. Tell your doctor straight away if you have any of these symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause.
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant during treatment and for 12 months afterwards. Use effective contraception during this time. You can talk to your doctor or nurse about this.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other, exceedingly rare side-effects may also be life-threatening.

Patient identifier/label

Statement of health professional

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for carboplatin and paclitaxel and/or individual drugs

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter (where appropriate)

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.

CANCER RESEARCH UK

Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (www.gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (www.doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: www.medicines.org.uk/emc
2. Cancer Research UK: www.cancerresearchuk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: www.macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Appendix 2. Example of a national SACT regimen-specific consent form (previous format): Carboplatin-Paclitaxel regimen for treatment of non-small cell lung cancer (NSCLC)

Patient agreement to systemic anti-cancer therapy (SACT):

Carboplatin-Paclitaxel

Patient details

Patient's surname/family name: _____

Patient's first name(s): _____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(e.g. other language/other communication method)

Hospital/NHS Trust/NHS Board: _____

Responsible consultant:

Name: _____

Job title: _____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ Carboplatin and paclitaxel chemotherapy for the treatment of non-small cell lung cancer (NSCLC) /thymoma*(*delete as appropriate)

☐ Given intravenously on day 1, every 21 days for 4 to 6 cycles OR

☐ Carboplatin and paclitaxel given intravenously. Carboplatin on day 1, and paclitaxel on day 1, 8 and 15, every 28 days for up to 6 cycles.

Where the treatment will be given

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Curative – to give you the best possible chance of being cured.

☐ **Disease control/palliative** – the aim is not to cure but to control or shrink the disease. The aim is to improve both quality of life and survival.

☐ **Adjuvant** – therapy given after surgery/radiotherapy to reduce the risk of the cancer coming back.

☐ **Neo-adjuvant** – therapy given before surgery/radiotherapy to shrink the cancer, allow treatment and reduce the risk of the cancer coming back

To be retained in patient notes
Prepared by Pharmacist
Checked by Pharmacist: SAMPLE
Checked by Consultant:

Date of issue and version: Version Review date:
Approved by: Janine Mansi UK Chemotherapy Board
Check www.cruk.org/sact_consent for latest version
Carboplatin- Paclitaxel

Patient identifier/label

Statement of health professional

(continued)

Significant, unavoidable or frequently occurring risks

Common side effects:

More than 10 in every 100 (>10%) people have one or more of the side effects listed:

- ☐ An increased risk of getting an infection from a drop in white blood cells - it is harder to fight infections and you can become very ill.
- ☐ If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:
  - your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team
  - you suddenly feel unwell (even with a normal temperature)
- ☐ Thinning of the hair or hair loss, tiredness and feeling weak (fatigue), feeling sick (nausea) and/or being sick (vomiting), watery or sore eyes, sore mouth and ulcers, abdominal (tummy) pain, diarrhoea, muscle and joint aches and pain which may be severe.
- ☐ Numbness or tingling in the hands and feet which may be temporary or permanent, low blood pressure during treatment, and fluid retention (you may notice weight gain and/or your ankles and legs swell).
- ☐ Paclitaxel may cause an allergic reaction while being given. You will have medicines before your treatment to help prevent this.
- ☐ Anaemia (due to red blood cells), bruising or bleeding (due to low platelets), low electrolyte levels (sodium, potassium, calcium and magnesium), changes in kidney and liver function tests.

Occasional side effects:

Between 1 and 10 in every 100 (1-10%) people have one or more of these effects:

- ☐ Ear problems (changes in hearing and uncommonly high frequency hearing loss which may be permanent, ringing in ears), eye problems (change in vision), nose bleed, loss of appetite, change in taste, low heart rate, constipation.
- ☐ Sore hands and feet (some people develop soreness, redness and peeling), rash and/or itching of the skin, nail changes.
- ☐ Pain, redness and swelling at the site of injection.
- ☐ Allergic reactions whilst having carboplatin are not common.

Other risks:

- ☐ All intravenous drugs may leak outside of the vein and damage the tissue around while being given (extravasation). Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein as, extravasation although uncommon, it's important that this is dealt with quickly.
- ☐ Occasionally hair loss may be permanent and nail loss temporary.
- ☐ Changes in the lung tissue may lead to cough,chest pain or breathlessness during or developing in the future. Let your doctor or nurse know if you have these symptoms while at rest or gentle activity.
- ☐ Paclitaxel contains alcohol. This may affect your ability to drive or operate machinery. If this is a problem tell your doctor, nurse or pharmacist.
- ☐ Potential side-effects with the anti-sickness medication may include: constipation, headaches, indigestion, difficulty sleeping and agitation.
- ☐ Steroids and some treatments for cancer can raise your blood sugar. This usually goes back to normal after your treatment. If you have diabetes, it may lead to higher blood sugar levels. Please ask your team/GP if concerned.
- ☐ Cancer and treatment for cancer can increase your risk of developing a blood clot (thrombosis). A blood clot may cause pain, redness and swelling in a leg, breathlessness, chest pain or a stroke. Tell your doctor straight away if you have any of these symptoms.
- ☐ Some anti-cancer medicines can damage women's ovaries and men's sperm. This may lead to infertility in men and women and/or early menopause in women.
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant during treatment and for 12 months afterwards. Use effective contraception during this time. You can talk to your doctor or nurse about this.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but, other, exceedingly rare side-effects may also be life-threatening.

Patient identifier/label

Statement of health professional

(continued)

Any other risks and information

_____

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient / outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available

If No please document reason here: _____

_____

The following written information has been provided:

☐ Information leaflets for carboplatin and paclitaxel and/or for individual drugs

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter (where appropriate)

Interpreter booking reference (if applicable): _____

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____

Job title: _____

To be retained in patient notes
Prepared by Pharmacist:
Checked by Pharmacist:
Checked by Consultant: SAMPLE

Date of issue and version: Version Review date:
Approved by: Janine Mans[illegible] Chemotherapy Board
Check www.cruk.org/sact_consent for latest version
Carboplatin- Paclitaxel

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have **had enough time to consider** my options and make a decision about treatment.

☐ **I agree** to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. Young people/children may also like a parent to sign here (see notes).

Patient's signature: _____ Date: _____

Name (PRINT): _____

Parent's/Witness' signature: _____ Date: _____

Name (PRINT): _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign /date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone **0808 800 4040**, Monday to Friday, 9am to 5pm. Alternatively visit **www.cruk.org** for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT. The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.

CANCER RESEARCH UK

To be retained in patient notes
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Checked by Pharmacist: SAMPLE
Checked by Consultant:

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Carboplatin- Paclitaxel

Patient identifier/label

Guidance for health professionals (to be read in conjunction with the hospital's consent policy)

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a check-list of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2008 (available at **www.gmc-uk.org/guidance**), and Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (available at s).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. If a child under the age of 16 has "sufficient understanding and intelligence to enable him or her to understand fully what is proposed", then the child will have capacity to give consent for himself or herself.
Young people aged 16 and 17, and younger children with capacity, may therefore sign this form for themselves, but may like a parent to countersign as well. If the child is not able to give consent, someone with parental responsibility may do so on their behalf and a separate form is available for this purpose. Even where children are able to give consent for themselves, you should always involve those with parental responsibility in the child's care, unless the child specifically asks you not to do so. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual, and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient is 18 or over and lacks the capacity to give consent, you should use an alternative form (form for adults who lack the capacity to consent to investigation or treatment). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so.

Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics (SmPCs) for individual drugs: https://www.medicines.org.uk/emc
2. Cancer Research UK: https://www.cancerresearchuk.org/about-cancer/cancer-in-general/treatment/cancer-drugs
3. Macmillan Cancer Support: https://www.macmillan.org.uk/information-and-support/treating/chemotherapy/drugs-and-combination-regimens
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

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Carboplatin- Paclitaxel

Appendix 3. Template Letter for Governance/Consent Committees

Name and address of provider organisation

Date

To: Chair of Governance/Consent committee

Dear Chair name,

Re: Systemic Anti-Cancer Therapy (SACT) regimen-specific consent forms

The UK Systemic Anti-Cancer Therapy Board has issued guidance relating to consent for SACT and has recommended the use of standardised SACT regimen-specific consent forms in the UK. To support this recommendation a national library of standardised SACT regimen-specific consent forms is being made available to all SACT providers in the UK via a website. This is to support SACT providers to adhere to best practice guidance, and address the recommendations and proposed actions in the National Chemotherapy Action Group (NCAG) 2009 report that are relevant to consent.

The [name of SACT group] have considered this recommendation and benchmarked our existing SACT consent practice against the national guidance. Our existing practice is [brief description of existing practice, e.g. use of Trust/DHSC generic consent forms]. Following this exercise the group have decided that they wish to adopt and implement use of the national SACT regimen-specific consent forms into local practice for the benefits 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.

I am writing to submit a proposal to use the national SACT regimen-specific consent forms at [name of provider organisation] in preference to our existing practice.

Yours sincerely,

Chair of SACT group

Enclosed: *Consent for Systemic Anti-Cancer Therapy (SACT): Guidance*, UK Systemic Anti-Cancer Board, February 2024.
Sample SACT regimen-specific consent form.
Local process for the use of SACT regimen-specific consent forms.