Healthcare Improvement Scotland

Guidance on Consent for Systemic Anti-Cancer Therapy (SACT) in Adults

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Contents

1 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 NHS Scotland standards and recommendations from national reports.
- Introduce and recommend the use of SACT regimen-specific consent forms for all adult patients.
- Provide guidance for NHS Boards 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.

Consent forms for SACT for children and young people are in development; additional guidance required for this group will be issued when consent forms are available.

1.2 Systemic Anti-Cancer Therapy (SACT) and consent

The use of SACT is increasing year on year, and the types of agents are growing with 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 agreement to treatment with SACT involves almost unique uncertainties, and the process of obtaining consent requires considerable expertise and carries specific responsibilities.

In accordance with guidance from the General Medical Council (GMC)[1], Scottish Government[2], Scottish Parliament[3] and Scottish Government Health Department[4] (SGHD) it is best ethical and legal practice that the prescription of SACT be supported by explicit consent, i.e. written, signed consent following a full discussion of the intended benefits and the associated risks with the patient.

Consent is the shared-decision making process by which patient and physician come to an agreement on treatment. The signing of the consent form indicates that this process has taken place. It does not, necessarily, indicate that the patient has full comprehension of the treatment procedures, aims and complications.

The process of consent should therefore be supported with a contemporaneous documentation in the patient record confirming this process has been completed and communications (e.g. to GP) have taken place.

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[1-16]. Specifically, this guidance endorses the approaches adopted by the Scottish Government through Realistic Medicine[6,15] and the Academy of Medical Royal Colleges through the Choose Wisely UK[7] initiative. In alignment with these approaches SACT consent facilitates shared-decision making between patients and health professionals, and supports a personalised, patient-centred and evidence-based approach to care[14,16].

Following the outcome of the *Montgomery* case in 2015 the law now requires a doctor 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"[5]; 'material risks' being defined as whether "a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it" (*Montgomery* v *NHS Lanarkshire*). Similarly, the SGHD Independent Advisory Group (Tayside Breast Cancer) (IAG) Report recommends that "patients must be explicitly informed of any variance from generally accepted standard SACT clinical practice, for informed consent to take place"[8]. Renewed procedural guidance, based on these existing guidance documents, recent UK case law, and current accepted best practice is given in section 4 of this guidance.

1.3 UK Chemotherapy Board / SACT Regimen-Specific Consent Forms National Steering Group

The UK Chemotherapy Board provides guidance, oversight and support for the continuing development of chemotherapy services in the UK. It was established in 2013 by The Royal College of Radiologists (RCR), the Royal College of Physicians (RCP), the Association of Cancer Physicians (ACP), the Royal College of Pathologists (RCPath), the British Oncology Pharmacy Association (BOPA) and the UK Oncology Nursing Society (UKONS). It has representation from across the four UK nations and from other organisations closely involved in chemotherapy services. The Board's strategic role includes co-ordinating work at national level to support commissioning and delivery of services locally and advising on the development and delivery of safe, high-quality chemotherapy services. It works collaboratively with other groups and organisations across the UK.

The SACT regimen-specific consent forms were developed initially by Guy's and St. Thomas' NHS Foundation Trust (GSTT) as part of a project funded by the South East London Cancer Network. Since 2016, Cancer Research UK (CRUK) have worked with GSTT to produce national standardised SACT regimen-specific consent forms. This work is overseen by the Systemic Anti-Cancer Therapy (SACT) Regimen-Specific Consent Forms National Steering Group (NCSG).

The UK Chemotherapy Board oversees the work of the NCSG and recommends the use of standardised SACT regimen-specific consent forms in the UK[9]. The aim is to support organisations to adhere to best practice guidance. Introduction and adoption of the national forms by organisations will confer the governance and quality benefits of standardised regimen-specific forms to all eligible patients.

For further information see CRUK website.

1.4 NHS Scotland: current status

SACT services in Scotland must adhere to standards laid out in CEL 30 (2012)[2]. Standard 2 relates to "Decision to treat, consent and information for patients" (see appendix I). Section 2.1.1 specifies that "the decision to initiate a new course of SACT is taken by a consultant oncologist/haematologist after discussion at a multi-disciplinary team (MDT) meeting, if appropriate. This is done in consultation with the patient or carer, where appropriate". The HIS national external review of SACT service delivery, published in 2017[10], demonstrated a high level of compliance with CEL 30 (2012) across NHS Scotland but also highlighted that there may be benefit in standardising the approach to consent across NHS Scotland. Divergent approaches across NHS Scotland, combined with new requirements from recent court rulings (*Montgomery v NHS Lanarkshire*) highlighted a need to standardise SACT consent. This was further supported by the recommendations in the SGHD IAG report[8].

Scottish Cancer Taskforce (SCT) asked HIS to take forward a national review of consent for SACT. This included a survey of current practice across NHS Scotland and a meeting with stakeholders from all cancer networks in Scotland, the chair of the UK NCSG and HIS public partners. There was a unanimous view that a standardised approach to consent would improve quality and consistency by improving shared decision making and reducing variation in approach.

The CRUK consent forms were adjusted to meet key requirements of best practice in NHS Scotland. Stakeholders confirmed support to adopt the CRUK/UK Chemotherapy Board approach to consent and a co-ordinated approach to implementation across NHS Scotland. Formal NHS Scotland representation on the UK NCSG was also secured. There is a clear schedule in place to deliver those updates, however, there will be a period during which the forms are being developed where older versions of the regimen specific consent forms will be in use. All versions available on the CRUK website are CEL 30, 2012 compliant and meet UK chemotherapy and patient care legal standards.

The SGHD IAG report acknowledges the ongoing work of this group and states that "All Boards must adopt the standardised approach to SACT consent once guidance is available to ensure national consistency in documentation of informed consent across Scotland." The following guidance also addresses the recommendation:

> **"**Patients must be explicitly informed of any variance from generally accepted standard SACT clinical practice, for informed consent to take place. The risks of treatment should also be discussed and this discussion recorded in the patient's record."

It was acknowledged by the stakeholder group that there will be considerable work required to implement the new consent form, however, it was recognised that this is outweighed by the benefits of a consistent approach to SACT consent across Scotland.

2 National SACT regimen-specific consent forms

The national SACT regimen-specific forms include a minimum set of data that is necessary for the patient or carer's information, and a minimum number of fields to be completed to support the process and identify the completion of responsibilities within the process. It is recognised that some organisations may have specific requirements within their own consent procedures outside the content of the forms. Those organisations may augment the recommended national forms, but content cannot be deleted and any additions made should not contradict original content included in the forms.

2.1 Routine SACT

National SACT regimen-specific consent forms are available for the vast majority of oncology and a growing library of haemato-oncology regimens that are in routine use within the UK for the treatment of adult patients with cancer. Generic SACT and immunotherapy regimen-specific consent form templates are available which may be used as an interim measure where a regimen specific form is not available. See appendix II for an example of a regimen-specific consent form.

The 'Guidance for health professionals' on page 5 of the form is based on English law. This will be updated to reflect Scottish law in due course. In the meantime NHS Scotland staff should refer to this guidance and local NHS Board guidance on consent aligned to the Scottish legal framework.

2.2 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 SACT must be sought in addition to the consent process for the clinical trial.

2.3 Chemo-radiation

These forms are designed specifically for the taking of consent for SACT. For instances where SACT is given in combination with radiotherapy, both treatments will require separate consent.

3 Guidance for the introduction of the national SACT regimen-specific consent forms by NHS Boards

The process for the introduction and local adoption of national SACT regimen-specific consent forms may differ, however key aspects for each Board to consider in relation to the local introduction of the forms are described below. The implementation should be led by the NHS Board's SACT Lead Clinician. All boards must adopt this standardised approach to SACT consent.

3.1 NHS Board SACT Group

This guidance document and the national regimen-specific consent forms should be tabled for discussion by the NHS Board SACT group, or equivalent. The group should benchmark their current SACT consent processes against this guidance and agree actions required to adopt the use of the national regimen specific forms. Where national regimen-specific consent forms are not available, NHS Boards are to use the generic SACT and generic immunotherapy forms. The SACT Lead Clinician may nominate a lead person(s) from the group 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 NHS Board Governance/Consent committee

The appropriate NHS Board committee should be consulted on the implementation plan for SACT consent as set out in this guidance.

3.3 Local process for use of the forms

This guidance should form the basis of a local standard operating procedure (SOP) for use of the regimen-specific consent forms. The SOP should describe the operational process for:

- Downloading and printing of the forms from the website, including appropriateversion control;
- Storage of blank forms;
- Giving the patient a copy of completed forms;
- Filing of completed forms in the patient record;
- Confirming completion of process and communications, and how these are documented in the patient record.

4 Guidance for the process of consent for SACT: Clinical use and completion of SACT regimen-specific consent forms

4.1 Definition of consent

Consent is the principle that a person must give permission before they receive any type of medical treatment, test or examination. Consent is a dynamic and reactive process resulting from dialogue and subject to changes in information and circumstances. In clinical settings, informed consent is a process by which a clinician and a patient agree on a course of treatment. For consent to be valid it must be voluntary (i.e. the decision must not be influenced by pressure from e.g. medical staff, friends or family) and informed and the person consenting must have the capacity to make the decision.

Informed consent is protected by the laws of clinical negligence, which set out rules on informing patients of risks, benefits and alternatives to proposed treatment. Failure to obtain consent from patients can infringe the patient's autonomy and violates their bodily integrity. The *Montgomery* ruling (2015) "asserts a new patient-centred standard by which disclosure of information to the patient is judged. A clinician, during the consent process, must take reasonable care to ensure that a patient is aware of any 'material' (relevant) risks involved in any recommended treatment, and of any reasonable alternative or variant treatments"[3].

Explicit consent is required for high-risk interventions, such as SACT. This includes a signed consent form and documentation of conversations about consent in the patient records.

It is important to note that the consenting process is an ongoing process and as such it is important that renewed consent is requested when required.

4.2 Who can take consent?

Once the decision to treat has been made by the responsible consultant, consent should be obtained by a trained and appropriately experienced healthcare professional.

The health care professional must be aware of their legal, ethical and professional responsibilities with regards to consent, in addition to local institution policies and procedures.

A competent healthcare professional will be determined by NHS board policy and processes but may be one of the following:

- A consultant or associate specialist medical or clinical oncologist or haematologist.
- A specialist registrar, clinical fellow or speciality doctor (staff grade) in oncology or haematology who has had specific training in consent for SACT.
- A non-medical prescriber with documentation of competency in consent and with specific training to prescribe the specific regimen for which the patient will consent.

4.3 Who can give consent?

This document does not seek to duplicate guidance given elsewhere and its scope does not cover situations where the ability to give informed consent is lacking due to impaired, or lack of capacity. In these instances, local policy for adults with incapacity is followed in line with the Adults with Incapacity (Scotland) Act 2000[11], the Mental Health (Care and Treatment) (Scotland) Act 2003[12], all other relevant pieces of legislation (including all revisions and updates) and accompanying codes of practice.

4.4 When should consent for SACT be taken?

Consent must be obtained and documented prior to the first cycle of a course[1] of SACT, other than in exceptional circumstances.

In normal circumstances there should be time (measured in days rather than hours) for the patient to consider the decision to undergo the treatment before consent is completed. It is acknowledged that within many cancer pathways, considerable discussion may have been held between a patient and their clinical nurse specialist or other healthcare professionals prior to a first consultation with the individual formally taking consent. Nevertheless, full explanation of risks and benefits must still be undertaken with the patient in their first consultation with the individual formally taking consent.

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, biopsy, and/or other test results).
- There is sufficient privacy to discuss any issues that may arise.
- The patient has had the opportunity and been encouraged to, involve a relative, representative, friend and/or carer.
- The patient and/or relative/friend/representative/carer has had an opportunity to ask any questions that they may have.

In exceptional circumstances, for example when there is a lack of capacity to consent or in cases of medical emergency, local policy for adults with incapacity is followed in line with the Adults with Incapacity (Scotland) Act 2000[11], the Mental Health (Care and Treatment) (Scotland) Act 2003 [12], all other relevant pieces of legislation (including all revisions and updates) and accompanying codes of practice. When such circumstances arise, this should be recorded appropriately in the patient record explaining the circumstances that made it exceptional or an emergency.

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 a requirement that this is achieved through a professional translation service.

4.5 How should consent for SACT be obtained and documented?

The SACT regimen-specific form is an aid to the discussions about treatment with SACT. Where there is no regimen specific form available the generic SACT or immunotherapy template should be used.

[1] A course is defined as a planned number of cycles of the same regimen, or a standard sequential treatment comprising planned numbers of cycles of more than one regimen.

Discussions will 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, are to be discussed with the patient in terms that they can understand.

It is advisable to record discussions between the patient and the clinician on 'material' (relevant) risks involved in any recommended treatment, and of any reasonable alternative or variant treatments to ensure there is clarity and agreement on the information the patient has been given.

Should patient specific circumstances require an alteration to the MDT plan (e.g. co-morbidities), or if there is a reason to vary from the clinical management guideline (CMG), this will need to be discussed with the patient and documented in the patient records.

Key aspects of the discussion to be documented are:

- The aims and intended benefits of the treatment.
- Alternative and variant options
- Any deviation from the cancer network clinical management guideline or SACT protocol, and the rationale for deviation. This should be noted on the consent form[2] and expanded upon in the patient record when required.
- 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.
- The common side-effects and life-threatening complications, even where these are rare.
    - The healthcare professional must take into account 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 the 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.

[2] There are two different regimen specific templates in use. New versions include a section for documenting CMG/protocol compliance. In older versions any deviation should be documented in the 'other risks' section on page 3.

The patient should sign the form, after a period of time given to consider the treatment 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.

4.6 Confirmation of consent

Consent is to be confirmed and documented prior to the administration of the first cycle of SACT. This confirmation is sought and documented at the pre-SACT assessment or prior to SACT administration by a competent chemotherapy nurse / nurse specialist / pharmacist.

The health care professional should ensure that the patient understands:

- 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.

Where a patient expresses doubt about proceeding with treatment the opportunity to have a second consultation with a suitably trained and experienced healthcare professional prior to commencing treatment should be offered.

The requirement for efficient delivery of cancer treatments and the need for urgent therapy should not be limited by the need for a second consultation. Hence, the requirement for a second consultation can be assessed by a competent chemotherapy nurse / nurse specialist / pharmacist prior to administration of the first cycle of SACT. If at this point the patient is unsure of specific aspects of treatment, they will not receive immediate treatment and an appointment with a suitably experienced healthcare professional will be arranged as soon as possible.

It is good practice to ensure ongoing consent from the patient throughout the planned course of treatment, although documentation is required only prior to the first cycle.

Renewed consent should be sought where there is a material change which was not discussed at the initial consent. A material change could be a change in the regimen and/or diagnosis

The patient should be able to withdraw their consent at any time. Where consent is withdrawn the withdrawal should be discussed and documented in full. It is advisable to have the patient confirm they are withdrawing their consent by signing a document detailing withdrawal of consent and discontinuation of treatment.

4.7 Consent process in the context of care across organisational boundaries

If a patient is reviewed and managed across board boundaries, or there is a transfer of care, the consent process should not be duplicated. A copy of the consent form should be made available to, or transferred to, the relevant board care provider.

The board, who is to become the care provider, should fully review the completed consent form to ensure the detail is still accurate and reflects the treatment to be given by that board. Renewed consent should be taken if there is a material change from those noted in the consent form.

5 Audit of consent procedures

Audit of compliance with standards for consent is already established as part of the SACT Services Governance Framework[9]. Periodic self-audit of consent procedures for SACT is recommended. As a minimum, the audit should include the following standards where 100% compliance should be seen:

- The appropriate consent forms are available for review
- For 'normal circumstances' where SACT consent process has been applied:
    - The name and job title of the responsible consultant 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 Acknowledgements, consultation and support

This NHS Scotland guidance document has been developed by the HIS SACT Governance Framework Short Life Working Group and a Consent Stakeholder Subgroup. (appendix III) in consultation with the Scottish Association of Medical Directors, Scottish Academy of Royal Colleges, NHS Scotland Directors of Pharmacy Group, Directors of Nursing, SGHD.

The document is based on the guidance ratified by the UK Chemotherapy Board[9] which has representation from the following National bodies:

- The Association of Cancer Physicians
- The Royal College of Radiologists
- The Royal College of Physicians
- The Royal College of Pathologists
- The UK Oncology Nursing Society
- The British Oncology Pharmacy Association.

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 References and bibliography

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Appendix I - Extract from CEL (30) 2012

2. DECISION TO TREAT, CONSENT AND INFORMATION FOR PATIENTS

2.1 Decision to Treat and Consent

2.1.1 The decision to initiate a new course of SACT is taken by a consultant oncologist/haematologist after discussion at a multi-disciplinary team (MDT) meeting, if appropriate. This is done in consultation with the patient or carer, where appropriate.

2.1.2 Selection of the SACT protocol is the responsibility of the consultant oncologist/haematologist, taking into account the patient's wishes, co-morbidities and life expectancy.

2.1.3 The consultant oncologist/haematologist or delegated deputy obtains written informed consent to treatment.

2.1.4 Consent is taken at an appropriate period of time after the patient has been provided with verbal and written information which includes the potential risks and anticipated benefits.

2.1.5 The treatment decision, treatment intent and the proposed patient specific management plan are documented in the patient's record and communicated to the GP within 14 days.

2.1.6 The performance status of the patient and any co-morbidities are documented in the patient's record.

Appendix II – Example of a national SACT regimen specific consent form

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

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)

- ☐ Abemaciclib for the treatment of breast cancer.
- ☐ Tablets are taken orally twice a day on a continuous basis. Treatment is supplied every 28 days (one cycle). Treatment is continued until disease progression or unacceptable toxicity.
- ☐ Abemaciclib will be given in combination with an aromatase inhibito (e.g. letrozole* or anastrazole*) or fulvestrant* (*delete as appropriate).

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.

Statement of health professional
(continued)

Patient identifier/label

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 you 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)
- ☐ Anaemia (low number of red blood cells), bruising or bleeding (due to low number of blood platelets), low white blood cell counts and an increased risk of getting infections.
- ☐ Feeling sick (nausea) and being sick (vomiting), sore mouth and ulcers, diarrhoea, poor appetite, changes in taste, dizziness, tiredness and feeling weak (fatigue), thinning of hair or hair loss, skin changes (rash, itching), and liver changes picked up in blood tests.

Occasional side effects:

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

- ☐ Cancer and having treatment with abemaciclib for cancer can increase your risk of developing a blood clot (thrombosis). A blood clot may cause pain, redness and swelling in a leg, or breathlessness and chest pain. Tell your doctor straight away if you have any of these symptoms.
- ☐ Watery eyes, dry skin and muscle weakness.

Other risks:

- ☐ Changes in lung tissue may lead to cough, chest pain or breathlessness. Let your doctor know if you have difficulty breathing or experience shortness of breath while at rest or gentle activity.
- ☐ 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. Early menopause can cause symptoms such as hot flushes, vaginal dryness.
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or father a child during treatment or for 6 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.

Statement of health professional
(continued)

Patient identifier/label

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 abemaciclib.

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record **(www.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. 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

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 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 **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. 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 forms.

Appendix III – Membership of the SACT Governance Framework Short Life Working Group (SLWG) and Consent Stakeholder Subgroup

SACT Governance Framework Short Life Working Group

John	Murphy (chair)	Consultant Haematologist	WoSCAN	NHS Lanarkshire
David	Cameron	SACT Lead Clinician	SCAN	NHS Lothian
Sally	Clive	Consultant Medical Oncologist	SCAN	NHS Lothian
Tracey	Cole	MCN Manager	WoSCAN	NHS Greater Glasgow and Clyde
Justine	Collie	Staff Nurse	NoSCAN	NHS Grampian
Lorraine	Cowie	MCN Manager	NoSCAN	NHS Grampian
Heather	Dalrymple	Lead Cancer Care Pharmacist	SCAN	NHS Lothian
Tracy	Davis	National Network Manager	MSN CYPC	NHS Fife
David	Dunkley	Public Partner		Healthcare Improvement Scotland
David	Dunlop	Senior Medical Office-Oncology		Scottish Government
Carla	Forte	Lead Cancer Pharmacist	WoSCAN	NHS Greater Glasgow and Clyde
Maureen	Grant	Lead Nurse	WoSCAN	NHS Greater Glasgow and Clyde
Angela	Jesudason	MSN Clinical Director	MSN	
Judith	Jordan	Clinical Pharmacist	NoSCAN	NHS Grampian
Alastair	Dr Lawrie	SACT Lead Clinician	NoSCAN	NHS Grampian
Murdina	MacDonald	Lead Cancer Nurse	SCAN	NHS Fife
Mary	Maclean	National Clinical Lead – Cancer Medicines		Healthcare Improvement Scotland
Peter	MacLean	Clinical Director Cancer Services	WoSCAN	NHS Ayrshire and Arran
Kate	McDonald	Regional Cancer Manager	SCAN	NHS Lothian
Winifred	Mclure	Inspector Independent Healthcare		Healthcare Improvement Scotland
John	Milne	Lead Pharmacist Oncology	WoSCAN	NHS Lanarkshire
Dermot	Murphy	Consultant Paediatric Oncologist	MSN CYPC	NHS Greater Glasgow and Clyde
Neil	Richardson	MSN Lead Pharmacist	MSN	NHS Lothian
Susan	Siegal	Public Partner		Healthcare Improvement Scotland
Evelyn	Thomson	Regional Manager Cancer	WoSCAN	NHS Greater Glasgow and Clyde
Gillian	Wilson	Senior Charge Nurse	SCAN	NHS Fife

SACT Consent Stakeholder Subgroup

John	Murphy (chair)	Consultant Haematologist	WoSCAN	NHS Lanarkshire
Sophie	Barrett	Consultant Medical Oncologist and SACT Lead	WoSCAN	NHS Greater Glasgow and Clyde
Emma	Brown	Consultant Oncologist and SACT Lead	NCA	NHS Tayside
Fiona	Campbell	Clinical Nurse Specialist	NCA	NHS Highland
Sally	Clive	Consultant Medical Oncologist	SCAN	NHS Lothian
Fiona	Cutler	Consultant Haematologist and SACT Lead	WoSCAN	NHS Ayrshire and Arran
Heather	Dalrymple	Lead Cancer Care Pharmacist	SCAN	NHS Lothian
Kerri	Davison	Consultant Haematologist	SCAN	NHS Fife
David	Dunkley	Public Partner		Healthcare Improvement Scotland
David	Dunlop	Senior Medical Officer		Scottish Government
Katrina	Farrell	Consultant Haematologist and SACT Lead	WoSCAN	NHS Forth Valley
Peter	Forsyth	Consultant Haematologist and SACT Lead	NCA	NHS Highland
Janet	Graham	Consultant Medical Oncologist	WoSCAN	NHS Greater Glasgow and Clyde
Alastair	Lawrie	Consultant Haematologist and SACT Lead	NCA	NHS Grampian
Mary	Maclean	National Clinical Lead – Cancer Medicines		Healthcare Improvement Scotland
Zor	Maung	Consultant Haematologist	SCAN	NHS Lothian
Michelle	McGachie	Project Officer		Healthcare Improvement Scotland
Louise	McKee	Pharmacist	NCA	NHS Grampian
Ann	McKenna	Haematology/Oncology Nurse Specialist	WoSCAN	NHS Lanarkshire
John	Milne	Lead Pharmacist Oncology	WoSCAN	NHS Lanarkshire
Dermot	Murphy	Consultant Paediatric Oncologist	MSN CYPC	NHS Greater Glasgow and Clyde
Neil	Richardson	Lead Pharmacist	MSN CYPC	NHS Lothian
Lesley	Simpson	Consultant Oncologist at RHSC	MSN CYPC	NHS Lothian
Ruth	Stephenson	Medical Reviewer		Healthcare Improvement Scotland
Gordon	Urquhart	Consultant Oncologist	NCA	NHS Grampian

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