Patient agreement to systemic anti-cancer therapy (SACT)

(1) (3) (3) (3)	Patient's first name(s):
Vinorelbine and	
Capecitabine	Date of birth:
	NHS number:
	(or other identifier)
Hospital/NHS Trust/NHS Board:	
nospita//NH3 Trust/NH3 Board.	Special requirements: (eg other language/other communication
	method)
Responsible consultant:	
Name:	
Job title:	
	<u> </u>
Name of proposed course of treatment (include brief explanation if medical term not clear)
☐ Vinorelbine and Capecitabine for the treatment	nt of breast cancer.
	(*delete as appropriate) on day 1 and 8. Capecitabine owed by a 7 day break). Each treatment cycle lasts for
*	e* OR Capecitabine* OR Vinorelbine and Capecitabine le side effects or withdrawal of consent (*delete as
Where will I have treatment?	
☐ Outpatient ☐ Day unit/case ☐ Inpatient	nt Other:
	<u> </u>
Statement of health profess	
(to be filled in by health professional with appropr the hospital/Trust/NHS board's consent policy)	riate knowledge of proposed procedure, as specified in
✓ Tick all relevant boxes	
☐ I confirm the patient has capacity to give cons	sent.
☐ I have explained the course of treatment and	
The intended benefits (there are no guarante	ees about outcome)
Curative – to give you the best possible chance	•
Disease control or palliative – the aim is not to both quality of life and survival.	o cure, but to control or shrink the disease and improve
	otherapy to reduce the risk of the cancer coming back.
	or radiotherapy to shrink the cancer, allow treatment

Patient details

Patient's surname/family name:

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and reduce the risk of the cancer coming back

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Statement of health professional

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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 lifethreatening. 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) Tiredness and feeling weak (fatigue). Feeling sick (nausea), being sick (vomiting), diarrhoea, constipation, tummy (abdominal) pain, taste changes, sore mouth and ulcers, appetite loss, weight loss. Soreness, redness and peeling on the palms of hands and soles of the feet, skin changes (rash, dryness, redness, itching, temporary darkening), thinning hair or hair loss. Numbness or tingling in the hands and feet (which may be temporary or permanent). Anaemia (low red blood cells), bruising and bleeding (due to low platelets), changes in how well the liver works (monitored with blood tests). Vinorelbine may cause pain, redness, discolouration along the vein when given intravenously. Occasional side effects: Affecting between 1-10 in every 100 (1-10%) people Nail changes, swelling in the hands and feet. Dry mouth, indigestion, passing wind, cough, coughing up blood, shortness of breath. Changes in kidney function tests (monitored), electrolyte changes eg low potassium, sodium, magnesium and calcium, high blood sugar levels – monitored. Headache, dizziness, difficulty sleeping, feeling sad, joint or muscle pain, jaw pain, watering eyes, a runny nose, nosebleeds. An allergic reaction to Vinorelbine (severe reactions are rare).	Other risks continued: □ Capecitabine may rarely cause heart problems (chest pain, irregular heart rate, heart attack) and stroke. □ A risk of potentially life-threatening side effects if your genetic make-up means that you cannot break down Capecitabine properly (DPD deficiency). Before you start treatment, you will have a genetic test to check for this. Tell your doctor /nurse/ pharmacist straight away if you get even minor side effects in the first cycle. □ Very rarely, a severe skin reaction with Capecitabine (Toxic Epidermal Necrolysis or Stevens-Johnson Syndrome). If you have sore red skin patches which blister and peel, seek urgent medical advice. Skin changes may be preceded by fever, chest infection symptoms and your eyes may be more sensitive to light. □ Side effects with anti-sickness medication: constipation, headaches, indigestion, difficulty sleeping and agitation. □ Before treatment, you might have blood tests to check for viruses such as Hepatitis B, Hepatitis C, HIV or more unusual infections. This treatment may weaken your natural defence (immune) system, so infections like this could worsen or become active again if you've had them in the past. You may have medicines to prevent or treat infection. □ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness, swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms. □ Changes in memory, concentration or ability to think clearly. There can be many causes of this. □ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (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 make someone else pregnant during treatment and for 7 months after. Use effective contraception throughout.	
sad, joint or muscle pain, jaw pain, watering eyes, a runny nose, nosebleeds. An allergic reaction to Vinorelbine (severe	important not to become pregnant or make someone else pregnant during treatment and for 7 months after. Use effective contraception	

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Statement of health professional

Patient identifier/label	
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Any other risks and information:		
☐ I have discussed the intended benefit and risks available alternative treatments (including no treatments)	·	
☐ I have discussed the side effects of the recomms straight away or in the future, and that there may be rare or have not yet been reported. Each patient may	e some side effects not listed because they are	
☐ I have discussed what the treatment is likely to it timing of the treatment, blood and any additional test	,	
☐ I have explained to the patient, that they have the should contact the responsible consultant or team in	·	
☐ I have discussed concerns of particular important	nce to the patient in regard to treatment	
(please write details here):		
The following written information has been provided: Information leaflet for Vinorelbine and Capecitabine	Health professional details: Signed: Date:	
☐ 24 hour alert card or SACT advice service contact details	Name (PRINT):	
SACT treatment record (cruk.org/treatment-record)	Job title:	
Other, please state:		
Statement of interpreter (where a Interpreter booking reference (if applicable): I have interpreted the information above to the patie believe they can understand.		
Signed:	Date:	
Name (PRINT):	Job title:	

Statement of patient

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your own copy of the form which describes the be	has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form.
☐ I have had enough time to consider my optio	ns 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 unab parental responsibility will be asked to sign for yo	ole to sign but has indicated their consent. A person with bung people under the age of 16 years.
Patient's signature:	
Name (PRINT):	Date:
Person with parental responsibility/witness' signa	ature:
Name (PRINT):	Date:
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 information for patients Contact details (if patient wishes to discuss options later):
further questions and wishes the course of treatment/procedures to go ahead.	Contact your hospital team if you have any questions about cancer and its treatment.
Signed: Date:	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
Name (PRINT):	
Job title:	
Important notes: (tick if applicable)	more information.
 ☐ See also advance decision to refuse treatment ☐ Patient has withdrawn consent (ask patient to sign and date here) 	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.
Signed:	The project is supported by
Date:	Cancer Research UK. This does not mean you are taking part in a clinical trial.

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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

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