Patient agreement to systemic anti-cancer

therapy (SACT)	Patient's first name(s):
Capivasertib	
•	Date of birth:
	NHS number:
Hospital/NHS Trust/NHS Board:	(or other identifier)
nospitai/iviis irust/iviis board.	Special requirements: (eg other language/other communication
	method)
Responsible consultant:	
Name:	
Job title:	
Name of proposed course of treatment (inc Capivasertib for the treatment of breast cancer.	lude brief explanation if medical term not clear)
Capivasertib is taken orally twice each day for 4 cycle.	days followed by 3 days off treatment in a 28 day
☐ Capivasertib is taken in combination with Fulves then every 28 days.	trant (given on day 1 and day 15 for the first cycle and
Treatment is continued until disease progression	•
If you are pre or peri-menopausal, you may also	have an injection called Goserelin OR Leuprorelin.
Where will I have treatment?	
	Other:

Patient details

Patient's surname/family name:

n the hospital/Trust/NHS board's consent policy)

$ \mathbf{V} $	Tick all	relevant	hoxes
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	I confirm	the na	atient h	as cana	acity to	avio	consent	
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☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

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	Curative –	to give	vou the	best	nossible	chance	of beina	cured
	-	9	<i>,</i>	2000	P000.0.0	0.10.100	0. 209	5 4.55

- 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

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Michal Sladkowski Checked by Consultant: Anne Armstrong

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Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:	Other risks:		
 Affecting more than 10 in every 100 (>10%) people □ Diarrhoea. □ Nausea (feeling sick), vomiting (being sick), loss of appetite. □ Sore mouth and ulcers. □ Tiredness and feeling weak (fatigue). □ Skin reactions ranging from rash, peeling or shedding, redness, itching. □ Anaemia (due to low red blood cells). □ Capivasertib can raise your blood sugar levels (which are monitored). Your doctor may need to prescribe medication to lower your blood sugar level if it becomes too high. If you have diabetes, blood sugars may be higher than usual. Symptoms include: feeling very thirsty, dry mouth, passing urine more than usual, tiredness, feeling sick, increased appetite with weight loss. □ Urinary tract infections. 	 Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms. Before treatment, you might have blood tests to check for viruses (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. Side effects with anti-sickness medication include constipation, headaches, indigestion, difficulty sleeping and agitation. Changes in memory, concentration or ability to think clearly. There can be many causes of this including your treatment, diagnosis, or both. Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility 		
Occasional side effects: Affecting between 1-10 in every 100 (1-10%) people Allergic reactions. Change in taste, heartburn. Dry skin. Changes in kidney function – monitored with blood tests.	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 at least 16 weeks after treatment. Use effective contraception throughout. 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

Patient identifier/label	Patient	identifier	/label
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Any other risks and information:		
☐ I have discussed the intended benefit and risks of available alternative treatments (including no treatments)		
☐ I have discussed the side effects of the recomme straight away or in the future, and that there may rare or have not yet been reported. Each patient	be some side effects not listed because they are	
☐ I have discussed what the treatment is likely to intiming of the treatment, blood and any additional	· • • • • • • • • • • • • • • • • • • •	
☐ I have explained to the patient, that they have the should contact the responsible consultant or team	·	
☐ I have discussed concerns of particular important (please write details here):	•	
Clinical management guideline/Protocol con	npliant (please tick): e document reason here:	
The following written information has been provided:	Health professional details: Signed:	
☐ Information leaflet for Capivasertib	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:		
	1	
Statement of interpreter (where applicable):	ppropriate)	
I have interpreted the information above to the patient believe they can understand.	t to the best of my ability and in a way in which I	
Signed:	Date:	

Statement of patient

Patient identifier/label

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	ble 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 questions and wishes the course of	patients Contact details (if patient wishes to discuss options later):		
treatment/procedures to go ahead. Signed:	Contact your hospital team if you have any questions about cancer and its treatment.		
Date:	Cancer Research UK can also help answer your		
Name (PRINT):	questions about cancer and treatment. If you want to talk in confidence, call our information		
Job title:	nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for		
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: Date:	The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.		

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taking part in a clinical trial.

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 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (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: medicines.org.uk/emc
- Cancer Research UK: cruk.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

Capivasertib