Patient agreement to systemic anti-cancer therapy (SACT)

Trastuzumab	
	Date of birth:
	NHS number:(or other identifier)
Hospital/NHS Trust/NHS Board:	Special requirements: (eg other language/other communication method)
Responsible consultant: Name:	
Job title:	
Name of proposed course of treatment (inclu	ide brief explanation if medical term not clear)
☐ Trastuzumab for the treatment of breast cancer.	
☐ Trastuzumab is given by intravenous* OR subcuta as appropriate).	aneous* injection every 21 days (one cycle) (*delete
☐ Treatment is continued for a total of 18 cycles (12	months).
OR	
☐ Treatment is continued until disease progression,	unacceptable side effects or withdrawal of consent.
Where will I have treatment? ☐ Outpatient ☐ Day unit/case ☐ Inpatient	Other:
Statement of health profession	

Patient details

Patient's surname/family name:

Patient's first name(s):

Statement of nealth 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)

$ \mathbf{V} $	Tick	all	re	levai	٦t	boxes
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□ I	confirm the	patient has	capacity to	give consen	ιt.
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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)

Curative –	to give you	the best	possible c	hance 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

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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	☐ If given by injection under the skin
☐ When Trastuzumab is given together with	(subcutaneously), Trastuzumab may cause
chemotherapy, there is an increased risk of	soreness at the injection site.
getting an infection from a drop in white blood	☐ If given intravenously, Trastuzumab may leak
cells – it is harder to fight infections and you	outside of the vein and damage the tissue
can become very ill.	around while being given (extravasation). Tell
☐ If you have a severe infection this can be life-	the nurse straight away if you have any
threatening. Contact your doctor or hospital	stinging, pain, redness or swelling around the
straight away if:	vein. It's uncommon but important to deal with
 your temperature goes over 37.5°C or 	quickly.
over 38°C, depending on the advice given	Inflammation of the lungs (pneumonitis) may
by your chemotherapy team	lead to a cough, chest pain or breathlessness.
you suddenly feel unwell (even with a	Tell your doctor if you have difficulty breathing
normal temperature)	or shortness of breath at rest or with gentle
Reactions may occur while treatment is being	activity.
given or within a few hours. They are usually	Before treatment, you might have blood tests to
the most noticeable with the first dose: flu-like	check for viruses such as Hepatitis B, Hepatitis
symptoms, high or low blood pressure, flushing,	C, HIV or more unusual infections. This
shortness of breath, feeling sick or being sick,	treatment may weaken your natural defence
faster or irregular heartbeat, allergic reactions	(immune) system, so infections like this could
(severe reactions are less common).	worsen or become active again if you've had
Diarrhoea, constipation, feeling sick (nausea),	them in the past. You may have medicines to
appetite loss, taste changes, tummy (abdominal) pain, heartburn, weight loss.	prevent or treat infection.
Tiredness and feeling weak (fatigue).	Cancer and its treatment can increase your risk
Skin or nail changes.	of developing a blood clot (thrombosis), causing
Numbness and tingling in the hands and feet.	pain, redness and swelling in an arm or leg,
Headaches, dizziness, difficulty sleeping.	breathlessness, chest pain. Tell your doctor
Changes in how well the heart works, irregular	straight away if you have any symptoms.
heart rhythm. You will have tests throughout	Changes in memory, concentration, or ability to
treatment to monitor your heart function (usually	think clearly. There can be many causes of this
an echocardiogram) and your blood pressure.	including your treatment, diagnosis, or both.
Anaemia (due to low red blood cells), bleeding	Some anti-cancer medicines can damage
or bruising (due to low platelets).	ovaries and sperm. This may lead to infertility
Aches and pain in joints, muscle, back and	and/or early menopause (hot flushes, vaginal
bone.	dryness).
Watering and sore eyes, blocked or runny nose	Some anti-cancer medicines may damage the
nosebleeds.	development of a baby in the womb. It is
Occassional side effects:	important not to become pregnant or make
Feeling anxious or depressed, feeling very	someone else pregnant during treatment and
sleepy.	for 7 months after. Use effective contraception.
Dry mouth, haemorrhoids	Complications of treatment can very
Stiff arms or legs.	occasionally be life-threatening and may result
Dry eyes, excessive sweating, itching.	in death. The risks are different for every
Changes in liver functions tests.	individual. Potentially life-threatening
Pain in hands and feet, muscle spasm	complications include those listed on this form,
Build-up of fluid in hands and feet.	but other exceedingly rare side effects may also
	be life-threatening.

Statement of health professional

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 treatment)	· · · · · · · · · · · · · · · · · · ·
☐ I have discussed the side effects of the recommendation of 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 if	•
☐ I have discussed concerns of particular importan	nce to the patient in regard to treatment
(please write details here):	
The following written information has been provided: Information leaflet for Trastuzumab	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 patier believe they can understand.	
Signed:	Date:
Name (PRINT):	Job title:

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	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 questions and wishes the course of	patients Contact details (if patient wishes to discuss options later): Contact your hospital team if you have any	
treatment/procedures to go ahead. Signed:	questions about cancer and its treatment.	
Date:	Cancer Research UK can also help answer your questions about cancer and treatment. If you	
Name (PRINT):	want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to	
Job title:	Friday, 9am to 5pm. Alternatively visit cruk.org for	
Important notes: (tick if applicable) See also advance decision to refuse treatment Patient has withdrawn consent (ask patient to sign and date here)	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.	
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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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

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