Patient agreement to systemic anti-cancer therapy (SACT)

(a) (a) (b) (b)	· ,				
Avelumab	Date of birth:				
	NHS number:				
	(or other identifier)				
Hospital/NHS Trust/NHS Board:	Special requirements: (eg other language/other communication method)				
Dannanaikla aanaultanti					
Responsible consultant: Name:					
Job title:					
•					
Name of proposed course of treatment (include	de brief explanation if medical term not clear)				
Avelumab for the treatment of Merkel cell carcinon	na.				
Avelumab is given intravenously every two weeks.					
Treatment is continued until disease progression, u	unacceptable toxicity or withdrawal of consent.				
Where will I have treatment? ☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐	Other:				
Statement of health profession					

Patient details

Patient's first name(s):

Patient's surname/family name:

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

I	✓	Tick all	relevant	hoxes

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The intended benefits (there are no guarantees about outcome)

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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	☐ Treatment uncommonly causes inflammation of:
Affecting more than 10 in every 100 (>10%) people This treatment acts on your immune system and can cause inflammation in parts of the body. This can cause severe side effects that can be life threatening. It's important to treat them quickly to stop them getting worse. Side effects may begin during treatment or months after. Treatment commonly causes inflammation of: Skin: rash, itch, redness, colour loss in patches (severe reactions causing blistering, peeling, sores, ulcers are less common) Stomach or intestine: tummy pain, diarrhoea, mucus or blood in the stools Joints and muscles: stiffness, aches, pain, arthritis Tiredness and feeling weak (fatigue), headache, high temperature (fever). Anaemia (due to low red blood cells). Feeling sick (nausea), being sick (vomiting), constipation, appetite loss, tummy (abdominal) pain, weight loss, dry mouth. Build-up of fluid causing swelling. Reactions while treatment is given and allergic reactions: flu-like symptoms, high or low blood pressure, flushing, shortness of breath, fast heartbeat, injection site pain. They are more common with the first 4 treatments. If you feel unwell, it is important to tell your nurse straight away. Your infusion may need to be temporarily interrupted to allow the reaction to settle down. The infusion may usually be continued. You may need to have additional medicines and the infusion may be given more slowly to prevent a reaction from happening again.	 □ Treatment uncommonly causes inflammation of: Liver: yellowing of the skin or eyes, dark urine, tummy pain Brain or nerves: confusion, memory problems, seizures, numbness, tingling, weakness Eyes: dry, itchy, watery eyes, pain, vision changes Pancreas: tummy pain, feeling or being sick Heart muscle: chest pain, palpitations, irregular rhythm, changes in heart function Bladder: frequent or painful urination, blood in the urine Rarely, the immune system may attack groups of blood cells and cause other blood conditions □ Side effects may need treatment with steroids or medicines to suppress the immune system. These medicines have side effects that are sometimes severe. You may need hormone replacement. These side effects may be permanent and need long-term treatment. □ All intravenous drugs may leak out of the vein and damage the tissue around it while being given (extravasation). It's uncommon but important to deal with quickly. Tell a nurse straight away if you have stinging, pain, redness, swelling around the vein. □ Cancer and its treatment can increase the risk of a blood clot (thrombosis) causing pain, redness, swelling in an arm or leg, breathlessness, chest pain, stroke. Tell your doctor straight away if you have symptoms. □ You may have blood tests to check for viruses such as Hepatitis B, Hepatitis C, HIV, or more unusual infections. Infections like these could
Occasional side effects:	worsen or become active again if you've had
Affecting between 1-10 in every 100 (1-10%) people	them in the past. You may need medicines to prevent or treat infection.
 Treatment occasionally causes inflammation of: Hormone glands (thyroid, pituitary, adrenal, pancreas): high or low thyroid hormone levels, headache, tiredness, irritation, blurred or double vision, forgetfulness, high blood sugars (rarely, diabetes which may be permanent) Lungs: breathlessness, cough Kidneys: changes in how well the kidneys work (monitored with blood tests) Bruising or bleeding (due to low platelets), low sodium levels (picked up in blood tests). High blood pressure. 	 Some anti-cancer medicines damage ovaries / sperm leading to infertility / early menopause. Some anti-cancer medicines damage the development of a baby in the womb. It's important not to become pregnant or make someone else pregnant during treatment and for 1 month after. Use effective contraception. 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.

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Statement of health professional

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		/Iauci

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 te	· • • • • • • • • • • • • • • • • • • •	
☐ I have explained to the patient, that they have the should contact the responsible consultant or team is	·	
☐ I have discussed concerns of particular important		
(please write details here):		
Clinical management guideline/Protocol co Yes No Not available If No pleas	mpliant (please tick): se document reason here:	
The following written information has been provided:	Health professional details: Signed:	
☐ Information leaflet for Avelumab	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 intermeder		
Statement of interpreter (where a	appropriate)	
Interpreter booking reference (if applicable): I have interpreted the information above to the patie believe they can understand.	nt to the best of my ability and in a way in which l	
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	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:
(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 guestions about cancer and treatment. If you
Name (PRINT):	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:	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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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