Patient agreement to checkpoint inhibitor immunotherapy

(Add name of regimen/protocol)

Hospital/NHS Trust/NHS Board:

Respon	nsible consultant:	
Name:		

Regimen: ____

Patient details		
Patient's surname/family name:		
Patient's t	first name(s):	
Date of bi	rth:	
NHS num (or other i		
•	equirements: language/other communication	

Name of proposed course of treatment (include brief explanation if medical term not clear. Include regimen or protocol name and list drug names in full. Specify the indication, route, schedule of administration and location of treatment.)

ndication for treatment (the cancer type):				
Route(s) of administration (tick all that apply):				
☐ Intravenous ☐ Subcutaneous ☐ Oral ☐ Other:				
Frequency (treatment days and length of cycle):				
Duration of treatment (number of cycles):				
☐ A separate consent form must be completed for radiotherapy				
☐ Participation in a clinical trial (trial name):				
Where will I have treatment?				
☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other				

Statement of health professional

The intended benefits (there are no guarantees about outcome)

- ☐ Curative to give you the best possible chance of being cured.
- \square 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: Lucy Cox
Checked by Consultant: Clare Barlow
Approved by: Janine Mansi UK SACT Board

Date of issue: Nov-23; Version: 3; Review date: Nov-26 Check cruk.org/sact_consent for latest version

Regimen/Protocol Name:

Statement of health professional

Patient identifier/label

To be retained in patient notes Prepared by Pharmacist: Lucy Cox Checked by Consultant: Clare Barlow Approved by: Janine Mansi UK SACT Board Date of issue: Nov-23; Version: 3; Review date: Nov-26 Check cruk.org/sact_consent for latest version Regimen/Protocol Name:

Statement of health professional

D-4:4	: -1 4:4:	/ _
Patient	identifier	/Ianai

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 recommendation and that there may be straight away or in the future, and that there may be straight away not yet been reported. Each patient may	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 test	, , ,			
☐ I have explained to the patient, that they have the should contact the responsible consultant or team if t	·			
☐ I have discussed concerns of particular important	ce to the patient in regard to treatment			
(please write details here):				
_				
24 hour alert card or SACT advice service contact details	Signed:			
been provided: Information leaflet for:	Signed: Date: Name (PRINT):			
been provided: Information leaflet for:	Signed: Date: Name (PRINT):			
been provided: Information leaflet for: 24 hour alert card or SACT advice service contact details SACT treatment record (cruk.org/treatment-record) Other, please state: Statement of interpreter (where ap Interpreter booking reference (if applicable):	Signed: Date: Name (PRINT): Job title:			
been provided: Information leaflet for: 24 hour alert card or SACT advice service contact details SACT treatment record (cruk.org/treatment-record) Other, please state: Statement of interpreter (where ap Interpreter booking reference (if applicable): I have interpreted the information above to the patient	Signed: Date: Name (PRINT): Job title:			
been provided: Information leaflet for:	Signed: Date: Name (PRINT): Job title:			

To be retained in patient notes Prepared by Pharmacist: Lucy Cox Checked by Consultant: Clare Barlow Approved by: Janine Mansi UK SACT Board Date of issue: Nov-23; Version: 3; Review date: Nov-26 Check cruk.org/sact_consent for latest version

Regimen/Protocol Name: _

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	Further information for 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 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 more information.	
Name (PRINT):		
Job title:		
Important notes: (tick if applicable)		
☐ 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.	

To be retained in patient notes Prepared by Pharmacist: Lucy Cox Checked by Consultant: Clare Barlow Approved by: Janine Mansi UK SACT Board Date of issue: Nov-23; Version: 3; Review date: Nov-26 Check cruk.org/sact_consent for latest version

Regimen/Protocol Name:

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

To be retained in patient notes
Prepared by Pharmacist: Lucy Cox
Checked by Consultant: Clare Barlow
Approved by: Janine Mansi UK SACT Board

Date of issue: Nov-23; Version: 3; Review date: Nov-26 Check cruk.org/sact_consent for latest version

Regimen/Protocol Name: