Patient agreement to **Patient details** systemic anti-cancer Patient's surname/family name: therapy (SACT) Patient's first name(s): Cisplatin-Paclitaxel -Pembrolizumab (+/-Date of birth: ___ NHS number: **Bevacizumab)** (or other identifier) Special requirements: **Hospital/NHS Trust/NHS Board:** (eg other language/other communication method) Responsible consultant: Job title: _____ Name of proposed course of treatment (include brief explanation if medical term not clear) Cisplatin - Paclitaxel - Pembrolizumab (+/- Bevacizumab) for the treatment of cervical cancer. A separate consent form must be completed for Bevacizumab. Cisplatin, Paclitaxel and Pembrolizumab given intravenously on day 1, every 21 days up to 6 cycles OR Cisplatin and Pembrolizumab intravenously on day 1, Paclitaxel intravenously on days 1, 8 and 15 every 21 days up to 6 cycles. Following 6 cycles, Pembrolizumab given intravenously as maintenance every 3 weeks* or 6 weeks* up to a maximum of 2 years or until disease progression. Where will I have treatment? ☐ Outpatient ☐ Day unit/case ☐ Inpatient Other: Statement of health 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) ☐ I confirm the patient has capacity to give consent.

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 chance 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

Cisplatin- Paclitaxel - Pembrolizumab (+/- Bevacizumab)

Statement of health professional

Patient identifier/label	

You may have one or more of the side effects listed

Common chemotherapy 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.	Occasional chemotherapy side effects continued: Paclitaxel may cause an allergic reaction while it's being given. You will have medicines before your treatment to help prevent this.
 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 team37.5°C or over 38°C, depending on the advice given by your chemotherapy team you suddenly feel unwell (even with a normal temperature) Hearing changes (ringing in the ears and uncommonly high frequency hearing loss which may be permanent), numbness or tingling in the hands and feet (which may be temporary or permanent). Thinning of the hair or sometimes complete hair loss, watery or sore eyes, sore mouth and ulcers, loss of appetite, feeling sick (nausea) and being sick (vomiting), taste changes, diarrhoea, tiredness and feeling weak (fatigue). Muscle and joint aches and pain which may be severe, mild allergic reactions (rash, flushing), low blood pressure during treatment, fluid buildup in legs and feet. Abnormal blood tests - Anaemia (due to low red blood cells), bruising or bleeding (due to low platelets), low sodium levels, changes in kidney function (monitored). 	Additional chemotherapy risks Allergic reactions while having cisplatin is not common. Lung tissue changes may lead to cough, chest pain or breathlessness. Let your doctor know if such symptoms at rest or during gentle activity. Paclitaxel contains alcohol. This may affect your ability to drive or operate machinery. Pembrolizumab side effects: 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 side effect quickly to stop them getting worse. Some side effects can begin during treatment or months after. Commonly, inflammation of: Stomach or intestine: tummy pain, diarrhoea, mucus or blood in the stools Skin: rash, itch, redness, colour loss (severe reactions causing blistering, peeling, sores, ulcers are rare) Joints and muscles: stiffness, aches, pain, arthritis Hormone glands (thyroid, pituitary, adrenal,
Occasional chemotherapy side effects: Affecting between 1-10 in every 100 (1-10%) people Low mood, feeling nervous, problem with sleeping, nose bleed, dry mouth, indigestion, bone and/or back pain, pain when passing urine. Changes in heart rhythm, low or high heart rate, changes in liver function picked up in blood tests. Sore hands and feet (some people develop soreness, redness and peeling on the palms of the hands and soles of the feet), rash and/or itching of the skin, nail changes (nail loss is temporary). Pain, redness, swelling at the site of injection.	headache, tiredness, irritation, blurred or double vision, forgetfulness, high blood sugars (rarely diabetes) Tiredness and feeling weak (fatigue), headache. Feeling sick (nausea), being sick (vomiting), appetite loss, dry mouth. Anaemia (due to low red blood cells). Changes in sodium, potassium and calcium levels (picked up in blood tests). High blood pressure. Occasionally, inflammation of: Lungs: breathlessness, cough Eyes: dry, itchy, watery eyes, pain, vision
	changes Continue to the next page

Statement of health professional

Pembrolizumab side effects (occasional) continued:

- Liver: yellowing of the skin or eyes, dark urine, tummy pain
- Kidneys: changes in how they work, which are monitored
- Difficulty sleeping.
- Build-up of fluid causing swelling.
- Uncommonly, inflammation of:
- Brain or nerves: confusion, memory problems, seizures, numbness, tingling, weakness
- · 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.

Other risks:

- ☐ Side effects may need treatment with steroids, hormones or medicines to suppress the immune system. They may be permanent and need long-term treatment. These medicines have side-effects that are sometimes severe.
- Side effects with anti-sickness medication include constipation, headaches, indigestion, difficulty sleeping, tremors and agitation.
- Steroids may increase blood sugar levels.
- All intravenous drugs may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.
- Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- 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.

Patient identifier/label

Other risks continued:

- Changes in your memory, concentration, ability to think clearly. There can be many causes of this including your treatment, diagnosis or both.
- Some anti-cancer medicines damage ovaries and sperm, which may cause infertility and/or 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 several months afterwards. 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

Any other risks and information:		
☐ I have discussed the intended benefit and risks alternative treatments (including no treatment).	of the recommended treatment, and of any available	
☐ I have discussed the side effects of the recomm straight away or in the future, and that there ma rare or have not yet been reported. Each patien	ay be some side effects not listed because they are	
☐ I have discussed what the treatment is likely to timing of the treatment, blood and any additional	involve (including inpatient/outpatient treatment, al tests, follow-up appointments etc) and location.	
☐ I have explained to the patient, that they have the contact the responsible consultant or team if the	he right to stop this treatment at any time and should ey wish to do so.	
☐ I have discussed concerns of particular importa (please write details here):	nce to the patient in regard to treatment	
Clinical management guideline/Protocol co	e document reason here:	
The following written information has been provided:	Health professional details:	
☐ Information leaflet for Cisplatin, Paclitaxel, Pembrolizumab (+/- Bevacizumab)	Signed:	
24 hour alert card or SACT advice service contact details	Name (PRINT):	
SACT treatment record (cruk.org/treatment-record)	Job title:	
Other, please state:		
	I	
Statement of interpreter (where Interpreter booking reference (if applicable):		
I have interpreted the information above to the patie believe they can understand.	ent to the best of my ability and in a way in which I	
Signed:	Date:	
Name (PRINT):	Job title:	

Statement of patient

Patient identifier/label

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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 will lestions, do ask – we are here to help you. You have the after you have signed this form.
☐ I have had enough time to consider my option	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	iture:
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)	Further information for patients Contact details (if patient wishes to discuss
On behalf of the team treating the patient, I have confirmed that the patient has no	options later):
further questions and wishes the course of 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 nurses on freephone 0808 800 4040, Monday to
lab Killa.	

This does not mean you are taking part in a clinical trial.

Job title:

treatment

Important notes: (tick if applicable)

☐ See also advance decision to refuse

Patient has withdrawn consent

(ask patient to sign and date here)

Signed:

Friday, 9am to 5pm. Alternatively visit cruk.org for

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

more information.

The project is supported by

Cancer Research UK.

to SACT.

CANCER

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:

- 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: www.medicines.org.uk/emc
- 2. Cancer Research UK: www.cancerresearchuk.org/aboutcancer/treatment/drugs
- understand information about the decision to be made³. 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