Patient agreement to **Patient details** Patient's surname/family name: systemic anti-cancer therapy (SACT) Patient's first name(s): Olaparib -Date of birth: **Bevacizumab** NHS number: (or other identifier) Special requirements: Hospital/NHS Trust/NHS Board: (eg other language/other communication method) Responsible consultant: Name: Job title: _____ Name of proposed course of treatment (include brief explanation if medical term not clear) Olaparib for the treatment of ovarian* / fallopian tube* / peritoneal* cancer. Olaparib taken orally twice a day and is supplied every 28 days (one cycle). Olaparib is continued for a maximum duration of two years or until disease progression or unacceptable side effects. \square Bevacizumab is given intravenously on day 1, every 21 days for a maximum duration of 15 months or until disease progression or unacceptable side effects. 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) ✓ Tick all relevant boxes ☐ 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

☐ 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

both quality of life and survival.

reduce the risk of the cancer coming back

Statement of health professional You may have one or more of the side effects listed

Patient identifier/label

Common 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. 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 team • you suddenly feel unwell (even with a	Other risks: Bevacizumab 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. Inflammation of the lungs (pneumonitis) may lead to a cough, chest pain or breathlessness. Tell your doctor if you have difficulty breathing or shortness of breath at rest or with gentle activity. Olaparib can cause a blood disorder which causes a drop in normal cell numbers
normal temperature) Anaemia (low red blood cells), bruising or bleeding (low platelets), low sodium and magnesium levels. Reduced appetite, dry or sore mouth and ulcers, taste changes, feeling sick (nausea) and being sick (vomiting), tummy (abdominal) pain, indigestion, diarrhoea, constipation. Shortness of breath, cough, feeling tired and weak (fatigue), numbness or tingling in hands and feet, speech changes. Aches, pain, weakness in muscles and joints, back pain, headache, dizziness, watery eyes, stuffy or runny nose, nose bleed. High blood pressure, slow wound healing, protein the urine, skin changes (dryness, redness, change in colour). This treatment can increase the risk of a blood clot (thrombosis) causing pain, redness, swelling in an arm or leg, chest pain, breathlessness. Tell your doctor straight away if you have symptoms. Occasional side effects: Affecting between 1-10 in every 100 (1-10%) people Changes in how well the liver and kidney works (monitored), dehydration, feeling drowsy. Flu-like symptoms or allergic reactions with Bevacizumab, during treatment or a few hours after (severe reactions are rare). Soreness, redness, peeling on the palms of hands or soles of the feet, hair thinning or loss. Changes heart rhythm and how the heart works. A bleed, hole, or abnormal opening in the intestine.	(myelodysplastic syndrome) or blood cancers (acute myeloid leukaemia) can occur. If you have low blood counts, your doctor may arrange a bone marrow check. Bevacizumab can cause healthy jawbone tissue to become damaged and die. Gum disease, denture problems, dental treatments can increase the risk. Very rare side effects with Bevacizumab include posterior reversible encephalopathy syndrome (PRES) where seizures, headache, altered mental status and visual disturbances have been described. Changes in your memory, concentration, or ability to think clearly. Before treatment, you might have blood tests to check for viruses such as 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. Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility 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 during treatment and for at least 6 months afterwards. Use effective contraception. Olaparib may also affect how well hormonal contraceptives work. 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

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 recomme straight away or in the future, and that there may rare or have not yet been reported. Each patient	y be 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	` • · · · · · · · · · · · · · · · · · ·	
☐ I have explained to the patient, that they have the contact the responsible consultant or team if the	ne right to stop this treatment at any time and should by wish to do so.	
☐ I have discussed concerns of particular important (please write details here):	nce to the patient in regard to treatment	
Clinical management guideline/Protocol co	mpliant (please tick):	
☐ Yes ☐ No ☐ Not available If No please	document reason here:	
The following written information has been provided:	Health professional details: Signed:	
☐ Information leaflet for Olaparib and Bevacizumab	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:		
	I	
Statement of interpreter (where a Interpreter booking reference (if applicable):	appropriate)	
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 I	
Signed:	Date:	
Name (PRINT):	Job title:	

Statement of patient

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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 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	ture:	
	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 information for patients	
	Contact details (if patient wishes to discuss	
	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 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	
Name (PRINT):		
Job title:		
Important notes: (tick if applicable)	·	
See also advance decision to refuse	nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.	

The project is supported by Cancer Research UK. **CANCER** This does not mean you are taking part in a clinical trial.

national project to support clinicians in ensuring

all patients are fully informed when consenting

Patient has withdrawn consent

(ask patient to sign and date here)

Date: ____

Signed:

to SACT.

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 made 3. 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