PATIENT AGREEMENT TO SYSTEMIC ANTI-CANCER THERAPY:
Cabazitaxel + Prednisolone

NAME OF PROPOSED COURSE OF TREATMENT (include brief explanation if medical term not clear)

☐ Cabazitaxel and prednisolone for the treatment of castrate refractory prostate cancer.
☐ Cabazitaxel is given intravenously on day 1, prednisolone tablets are taken orally on days 1 to 21 (that is continuously), every 21 days for up to 10 cycles.

WHERE THE TREATMENT WILL BE GIVEN:
☐ 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’s consent policy)

I have explained the procedure/treatment to the patient. In particular, I have explained:

☑ all relevant boxes

THE INTENDED BENEFITS
☐ CURATIVE – to give you the best possible chance of being cured.
☐ DISEASE CONTROL/PALLIATIVE – the aim is not to cure but to control or shrink the disease.
☐ ADJUVANT – therapy given after surgery to reduce the risk of the cancer coming back.
☐ NEO-ADJUVANT – therapy given before surgery/radiotherapy to shrink the cancer, allow radical treatment and reduce the risk of the cancer coming back.
COMMON SIDE EFFECTS:
More than 10 in every 100 (>10%) people have one or more of the side effects listed:

- Diarrhoea, feeling sick (nausea) and being sick (vomiting), abdominal (tummy) pain and constipation, taste changes, loss of appetite, anaemia (low number of red blood cells), bruising or bleeding, tiredness and feeling weak (fatigue), hair loss, changes in the lungs causing breathlessness and cough, back pain, aching or pain in joints and muscles, and small amounts of blood in the urine.

- 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 life threatening. Contact your doctor or hospital straight away if:
- your temperature goes over 37.5°C (99.5°F) or over 38°C (100.4°F), depending on the advice given by your chemotherapy team
- you suddenly feel unwell (even with a normal temperature)

OCCASIONAL SIDE EFFECTS:
Between 1 and 10 in every 100 (1-10%) people have one or more of these effects:

- Indigestion and heart burn, dry mouth, sore mouth and ulcers, headaches, dizziness, changes in blood pressure during treatment, dry skin, rashes, ringing in the ears, hot flushes and sweats, changes in heart rate, swelling of the hands and feet (fluid retention), and changes in the way the liver and kidneys work. Numbness and tingling in the hands and feet, which may be temporary or persistent.

- Cabazitaxel may cause an allergic reaction while being given. You will have medicines before your treatment to help prevent this.

OTHER RISKS:
- Cabazitaxel may leak outside of the vein while it is being given; this is called extravasation. If this happens when you’re having cabazitaxel it can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. Extravasation is not common but if it happens it’s important that it’s dealt with quickly.

- A potentially serious but very rare side-effect is gastrointestinal perforation (a tear or hole) in the stomach or intestines, contact your doctor if you experience sudden intense abdominal/tummy pain.

- Long term use of steroids (prednisolone) may cause irritation of the stomach lining, increase your appetite, cause changes in blood sugar levels, fluid retention, changes in behaviour (mood swings, difficulty sleeping, anxiety or irritability), eye changes, Cushing’s syndrome (acne, puffiness of the face, dark marks on the skin), muscle wasting and bone thinning (osteoporosis).

- Potential side-effects with the anti-sickness medication may include: constipation, headaches, indigestion, difficulty sleeping, and agitation.

- Cancer can increase your risk of developing a blood clot (thrombosis), and having treatment with anti-cancer medicines may increase this risk further. A blood clot may cause pain, redness and swelling in a leg, or breathlessness and chest pain - you must tell your doctor straight away if you have any of these symptoms.

- Some anti-cancer medicines can damage men’s sperm. This may lead to infertility in men.

- Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to father a child while you are having treatment and for up to 6 months afterwards. It is important to use effective contraception during and for up to 6 months after treatment. You can talk to your doctor or nurse about this.

- Very rarely complications of treatment with anti-cancer medicines can be life-threatening or even result in death. The risks are different for every individual. You can talk to your doctor or nurse about what this means for you.
STATEMENT OF HEALTH PROFESSIONAL (continued)

ANY OTHER RISKS:

☐ I have discussed what the treatment is likely to involve (including inpatient / outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.
☐ I have discussed the intended benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

THE FOLLOWING LEAFLET HAS BEEN PROVIDED:

☐ Information leaflet for cabazitaxel chemotherapy.
☐ 24 hour chemotherapy service contact details
☐ Other, please state: ________________________________

Signed: ________________________________ Date: ________________________________
Name (PRINT): ________________________________
Job title: ________________________________

STATEMENT OF INTERPRETER (where appropriate)

INTERPRETER BOOKING REFERENCE (if applicable): ________________________________

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

Signed: ________________________________ Date: ________________________________
Name (PRINT): ________________________________
Job title: ________________________________
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 with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signed: ____________________________________________
Date: ____________________________________________
Name (PRINT): ______________________________________
Job title: __________________________________________

IMPORTANT NOTES: (tick if applicable)

☐ See also advance decision to refuse treatment
☐ Patient has withdrawn consent
   (ask patient to sign /date here)

Signed: ____________________________________________
Date: ____________________________________________

COPY ACCEPTED BY PATIENT: YES / NO
(please circle)
GUIDANCE FOR HEALTH PROFESSIONALS
(to be read in conjunction with the hospital’s consent policy)

WHAT A CONSENT FORM IS FOR
This form documents the patient’s agreement to go ahead with the investigation or 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, however, 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 Department of Health’s Reference guide to consent for examination or treatment 2nd Edition for a comprehensive summary of the law on consent (also available at 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. If a child under the age of 16 has "sufficient understanding and intelligence to enable him or her to understand fully what is proposed", then he or she will have capacity to give consent for himself or herself. Young people aged 16 and 17, and younger children with capacity, may therefore sign this form for themselves, but may like a parent to countersign as well. If the child is not able to give consent for himself or herself, someone with parental responsibility may do so 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.

WHEN NOT TO USE THIS FORM
If the patient is 18 or over and lacks the capacity to give consent, you should use an alternative form (form for adults who lack the capacity to consent to investigation or treatment) instead of this form. A patient lacks capacity if they have an impairment of the mind or brain or disturbance affecting the way their mind or brain works and they cannot:
- 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.

Relative 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 the 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. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are 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.

REFERENCES
1. Summary of Product Characteristics (SPCs) for individual drugs: https://www.medicines.org.uk/emc/
4. Guy’s and St. Thomas’ NHS Foundation Trust, Chemotherapy consent forms.

TO BE RETAINED IN PATIENT NOTES
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Check www.cruk.org/sact_consent for latest version