Patient agreement to systemic anti-cancer therapy (SACT):

Nivolumab

Patient details

Patient's surname/family name: _____

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(e.g. other language/other communication method)

_____

_____

_____

_____

_____

_____

Hospital/NHS Trust/NHS Board: _____

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ Nivolumab for the treatment of renal cell carcinoma.

☐ Nivolumab is a type of immunotherapy which binds to a protein called PD-1 on the immune cells. This binding helps to stimulate the immune system to fight cancer cells.

☐ Given intravenously on day 1, every 14 days* OR 28 days* (*delete as appropriate).

☐ Treatment is continued until disease progression or unacceptable toxicity.

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/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/palliative** – the aim is not to cure but to control or shrink the disease. The aim is to improve both quality of life and survival.

☐ **Adjuvant** – therapy given after surgery/radiotherapy to reduce the risk of the cancer coming back.

☐ **Neo-adjuvant** – therapy given before surgery/radiotherapy to shrink the cancer, allow treatment and reduce the risk of the cancer coming back

Statement of health professional

(continued)

Patient identifier/label

Significant, unavoidable or frequently occurring risks

Common side effects:

More than 10 in every 100 (>10%) people have one or more of the side effects listed:

- ☐ Tiredness and feeling weak (fatigue), feeling sick (nausea), diarrhoea, skin reactions (rash and itching).
- ☐ Anaemia (due to low red blood cells), bleeding or bruising (due to low platelets), neutropenia (due to low white cells).
- ☐ Changes in liver and kidney function, abnormal electrolyte levels (sodium, potassium, magnesium, calcum), increase in enzymes (lipase and amylase) which helps to breakdown fat and carbohydrate.
- ☐ Nivolumab can raise your blood sugar. If you have diabetes, it may lead to higher blood sugar levels. Please ask your doctor/nurse/GP if concerned.

Occasional side effects:

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

☐ Immune related effects:

Nivolumab acts on your immune system and may cause inflammation in parts of the body. This can sometimes cause severe side-effects which may be life-threatening. It is important that any side-effects are treated when they occur to stop them from getting worse.

- Inflammation in the stomach or intestines (causing stomach pain, diarrhoea, and mucus or blood in the stools).
- Inflammation of the lungs causing breathlessness or cough.
- Inflammation of hormone producing glands (particularly pituitary, adrenal and thyroid). Symptoms include headaches, blurred/double vision, extreme tiredness, decreased sexual drive and becoming irritable and forgetful.
- Inflammation of the nerves: muscle weakness, numbness or tingling, dizziness or loss of consciousness.
- Inflammation of the liver (causing yellowing of the skin, eyes, dark urine or pain on the right side of the stomach.
- Inflammation of the eyes: redness or pain or loss of vision.

Occasional effects continued:

- Inflammation of the kidney: changes in kidney function picked up in blood tests.

☐ Other effects:

- Skin changes (white patches, dryness and redness), aches and/or discomfort in muscles, bones and joints, swelling in the hands, feet and/or face.
- High blood pressure, high magnesium and sodium levels.
- Infusion-related reactions include allergic reactions (causing a high temperature, chills, shivering (rigors) and pain at the site of the infusion.

Other risks:

- ☐ Steven Johnson syndrome or Toxic Epidermal Necrolysis, a severe skin reaction is rare. Inform your doctor or nurse straight away if you experience tender red skin patches which subsequently blister and peel.
- ☐ Cancer and treatment for cancer can increase your risk of developing a blood clot (thrombosis). A blood clot may cause pain, redness and swelling in a leg, or breathlessness and chest pain. Tell your doctor straight away if you have any of these symptoms.
- ☐ Some anti-cancer medicines can damage women's ovaries and men's sperm. This may lead to infertility in men and women and/or early menopause in women.
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or father a child during treatment and for 5 months afterwards. Use effective contraception during this time. You can talk to your doctor or nurse about this.
- ☐ 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

(continued)

Patient identifier/label

Any other risks and information

_____

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ 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 explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available

If No please document reason here: _____

_____

The following written information has been provided:

☐ Information leaflet for nivolumab

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

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 they can understand.

Signed: _____ Date: _____

Name (PRINT): _____

Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have **had enough time to consider** my options 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 unable to sign but has indicated their consent. Young people/children may also like a parent to sign here (see notes).

Patient's signature: _____ Date: _____

Name (PRINT): _____

Parent's/Witness' signature: _____ Date: _____

Name (PRINT): _____

Copy accepted by patient: yes / no (please circle)

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 treatment/procedures 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: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

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 **www.cruk.org** for more information.

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

CANCER RESEARCH UK

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 check-list 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 2008 (available at **www.gmc-uk.org/guidance**), and Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (available at **s**).

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 the child 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, someone with parental responsibility may do so on their behalf and a separate form is available for this purpose. Even where children are able to give consent for themselves, you should always involve those with parental responsibility in the child's care, unless the child specifically asks you not to do so. 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 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). 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 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.

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 (SmPCs) for individual drugs: https://www.medicines.org.uk/emc
2. Cancer Research UK: https://www.cancerresearchuk.org/about- cancer/cancer-in-general/treatment/cancer-drugs
3. Macmillan Cancer Support: https://www.macmillan.org.uk/information-and-support/treating/chemotherapy/drugs-and-combination-regimens
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form