PATIENT AGREEMENT TO SYSTEMIC ANTI-CANCER THERAPY: FOLFIRINOX

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

- Oxaliplatin, irinotecan and fluorouracil chemotherapy for the treatment of cancer of the pancreas.
- Oxaliplatin, irinotecan and fluorouracil are given intravenously. Oxaliplatin and irinotecan are given by infusion on day 1, fluorouracil is given by injection on day 1 and then by continuous infusion over 46 hours.
- Treatment is given every 14 days (1 cycle) for 6 to 12 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. The aim is to improve both quality of life and survival.

☐ 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), loss of appetite, abdominal (tummy) pain, sore mouth and ulcers, bruising and bleeding, anaemia (low number of red blood cells), tiredness and feeling weak (fatigue), hair loss, changes in heart rhythm, allergic reactions, and changes in the way the liver works (usually temporary).

- 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)

- Acute cholinergic syndrome occurring during or within the first 24 hours after the irinotecan infusion. The effects include diarrhoea (which may be severe), sweating, stomach cramps, increased production of saliva, and watery eyes. You may be given an injection of atropine before the irinotecan infusion to reduce these side effects.

- Numbness or tingling in the hands or feet particularly related to the cold, which may be temporary or persistent.

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

- Skin changes, rashes, sensitivity of the skin to sunlight, nail changes, sore hands and feet (some people develop soreness, redness and peeling on the palms of the hands and soles of the feet), and gritty or sore eyes and blurred vision.
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: ____________________________

THE FOLLOWING LEAFLET HAS BEEN PROVIDED:

☐ Information leaflet for oxaliplatin-irinotecan-fluorouracil (FOLFIRINOX) chemotherapy and/or for the individual drugs.
☐ 24 hour chemotherapy service contact details

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

☐ Other, please state: ____________________________

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: ____________________________

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.
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: __________________________

FURTHER INFORMATION FOR PATIENTS

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

TO BE RETAINED IN PATIENT NOTES
Prepared by Pharmacist: Victoria Fashina
Checked by Pharmacist: Yvonne Law
Checked by Consultant: Paul Ross

Date of issue and version: Aug-17; Version 1;
Review date: Aug-20
Approved by: Janine Mansi (National Chemotherapy Board)
Check www.cruk.org/sact_consent for latest version
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 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 and a separate form is available for this purpose. Even where a child is able to give consent for himself or herself, 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) 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.

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.

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.