Patient Agreement to Systemic Therapy: Consent Form

Irinotecan + Modified de Gramont (Folfiri)

Patient's details / addressograph:	☐ Male ☐ Female
	Special requirements (e.g. other language/other communication method)
	Consultant:

Name of proposed course of treatment: Irinotecan + Modified de Gramont (Folfiri)
Irinotecan IV infusion on day 1
Calcium folinate IV infusion on day 1
Fluorouracil IV bolus injection on day 1, then continuous infusion over 46 hours in a portable infusion device, also starting on day 1
All repeated every 2 weeks for 6 to 12 cycles
Macmillan leaflet(s) given ☐

Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

☐ I have discussed what the treatment is likely to involve (including inpatient / outpatient treatment, timing of the treatment, follow-up appointments) and location.

The intended benefits

☐ Curative – to give you the best possible chance of being cured
☐ 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 recurrence of cancer
☐ Neo-adjuvant – therapy given before surgery or radiotherapy to shrink the cancer

Significant, unavoidable or frequently occurring risks:

Common side-effects: increased sweating, production of saliva, stomach cramps and diarrhoea (occasionally severe), bruising and bleeding, anaemia (low number of red blood cells), feeling sick (nausea) and being sick (vomiting), loss of appetite, tiredness and feeling weak, hair loss, sore mouth and ulcers, taste changes.

Less common but potentially life threatening side-effects: chest pain or angina, and reduced resistance to infection which can lead to a potentially fatal blood infection.

Other less common side-effects include: nail changes, muscle cramps, soreness and redness of the palms of the hand and soles of the feet, sensitivity of the skin to sunlight, temporary effect on liver function, watery or sore eyes.

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

Some chemotherapy drugs can damage women's ovaries and men's sperm, with risk of infertility and early menopause in women. I have warned the patient about the likelihood of:

☐ early menopause in women ☐ infertility (in men and in women)

Some chemotherapy drugs may damage the development of a baby in the womb (foetus), leading to the many risks associated with an abnormal pregnancy. Therefore, I have discussed the issues of protected sex. This is an issue for both men and women. The patient has been advised not to become pregnant / not to get a partner pregnant during the period of treatment, and for 12 months (women) / 6 months (men) after treatment has completed.

Any other risks:

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Clinician Signature

Signed…… Date ……

Full Name (print) ……..…. / …… Job Title……..
(Forename) (Surname)

Statement of patient

Patient Signature

Please read this form carefully, which describes the benefits and risks of the proposed treatment. You have the right to change your mind at any time, including after you have signed this form.

I agree to undergo chemotherapy. I understand the treatment and am aware of the potential side-effects arising from this treatment.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate training and experience.

Signed…… Name……..……..

Date…….....

A witness should sign below if the patient is unable to sign but has indicated his or her consent.

Signature …… Date ……..…..……

Name (PRINT) ……..……

Statement of interpreter (where appropriate)

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 ……..…..… Name (PRINT) ……..……..…… Date……

Confirmation of consent **(to be completed by the chemotherapy nurse when the patient attends for the first cycle)**

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the treatment to go ahead.

Signed ……..…..… Name (PRINT) ……..……..…… Date……

Copy accepted by patient: yes/no (please ring)
Copy to be retained in patient's notes