Patient Agreement to Systemic Therapy: Consent Form

CTD

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

Name of proposed course of treatment: CTD
Cyclophosphamide oral once daily on days 1, 8, 15 and 22 of the cycle, Thalidomide oral once daily continuously, Dexamethasone oral once daily on days 1 to 4 and days 15-18 for the first three cycles and then on days 1-4 for the last three cycles

Repeated every 28 days for up to 6 cycles
Macmillan/CRUK leaflet given ☐
Thalidomide Information given and counselled on pregnancy prevention ☐

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

☐ Disease control - the aim is not to cure but to control the disease, and to achieve a remission. The aim is to improve both quality of life and survival

Significant, unavoidable or frequently occurring risks:

Common side-effects: low white blood cells (neutropenia) with risk of infection, low red blood cells (anaemia), low platelets with risk of bleeding, feeling sick (nausea), constipation, numbness or tingling in hands or feet, dizziness and fainting, slower heart rate, tiredness, sleepiness and feeling weak, mild hair loss, dry skin, rash.

Side effects related to dexamethasone: irritation of the stomach lining, increased appetite, changes in blood sugar levels, fluid retention, changes in behaviour (mood swings, difficulty sleeping, anxiety or irritability)

Less common but potentially life threatening side-effects: severe infection causing organ failure

Other less common side-effects include: sore mouth and ulcers, taste changes, irritation of the bladder lining. Late effects include a very rare chance of a second cancer

Cancer can increase your risk of developing a blood clot (thrombosis), and having chemotherapy may increase this risk further. Blood thinning medication is used during treatment to reduce this risk.
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 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)

Thalidomide can 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 CTD treatment. 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