Patient Agreement to Systemic Therapy: Consent Form

Rituximab IV infusion

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

Name of proposed course of treatment: Rituximab

☐ Rituximab mono-therapy; IV infusion on day 1, repeated every week for 4 doses

☐ Rituximab mono-therapy; IV infusion on day 1, repeated every 4 weeks for up to 6 doses

☐ Rituximab in combination with chemotherapy; IV infusion on day 1, repeated every 3- 4 weeks depending on the chemotherapy, for up to 6 cycles

☐ Rituximab maintenance treatment; IV infusion on day 1, repeated every 2 or 3 months, for up to 2 years

Macmillan/CRUK/other 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

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

☐ Curative – to give you the best possible chance of being cured

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms

Significant, unavoidable or frequently occurring risks:

Common side-effects: infusion-related side-effects include flu-like symptoms (high temperature, chills, muscle aches, tiredness, dizziness and headache), low blood pressure, flushing, and allergic reactions.

You will notice these symptoms while the drug is given or within 1-3 hours and they are usually most noticeable with the first infusion and are less noticeable with following doses.

Less common side-effects: Rituximab can cause a reduction in the function of the immune system. This can, very rarely, lead the development of serious infections, especially viral infections.

Rituximab 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)

Rituximab 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:…….
……..

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 Rituximab 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