This document has been approved for use at: [ ]

OFF-LABEL USE OF RITUXIMAB

PATIENT CONSENT FORM

Pharmaceutical companies need approval from the Therapeutic Goods Administration (TGA) to market medicines in Australia. A pharmaceutical company may not request approval from the TGA for every illness that the medicine could help. This has happened with rituximab. Rituximab has TGA approval for use in only a few illnesses. The rituximab Product Information lists these approved illnesses. Off-label use happens when a medicine is used outside its approved illnesses.
The doctor will explain how rituximab might help your illness and any side effects. Then the doctor will request consent from the patient (and/or their carer) before any off-label use.

PATIENT CONSENT

By signing this form, I, . *(write name of patient or person responsible)*, understand that:

- rituximab is not approved for use in Australia for the treatment of: (*write name of condition*)
- the effect and safety of rituximab in treating this condition may not be fully known;
- even while being very careful, unplanned issues may occur;
- there is a chance of having known and unknown side effects with the use of rituximab;
- during rituximab therapy, there are possible effects on immunisation status for me/the person I am responsible for.

I confirm that I have had the opportunity to ask questions. I am satisfied with the explanation and the answers to my questions.
I understand that I can change my mind and withdraw this consent to treatment with rituximab at any time.
With this knowledge, I **consent** to the use of rituximab in the treatment of me/the person I am responsible for.

Patient's name: **Patient's MRN:**

Signature of patient (or person responsible*): _____ **Date:**

***If the person responsible has signed, please provide details below:**

Name: **Date of Birth:**

Address: **Contact Number:**

Relationship to patient: **Reason for representation:**

If applicable, name & signature of witness: _____ **Date:**

Witness is not to be a member of the treating team. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

DOCTOR'S DECLARATION

I have provided to the patient/person responsible:

☐ an explanation of the off-label use of rituximab and its potential benefits and safety considerations;

☐ an explanation regarding vaccinations and impact on immunisation status during rituximab therapy; and,

☐ an Off-Label Rituximab Patient Fact Sheet.

I believe the information has been understood.

Doctor's name: **Designation:**

Signature: _____ **Date:**

INTERPRETER USE

Use an accredited Health Care Interpreter if the patient cannot converse adequately in English. Do not rely on relatives or other parties for interpreting. **Interpreter required:** ◯Yes /◯No

Language: **Name of interpreter:**

Employee ID: **Signature:** _____ **Date:**

Completed signed form should be kept in the patient's Health Record.

NSW TAG NSW Therapeutic Advisory Group Inc. Advancing quality use of medicines in NSW