This document has been approved for use at [Click here to enter text.]

# **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, Click here to enter text. *(write name of patient or person responsible),* understand that:

* rituximab is not approved for use in Australia for the treatment of: Click here to enter text. (*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.

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| 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:**  Click here to enter text. **Patient’s MRN:**  Click here to enter text.  **Signature of patient (or person responsible\*):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** Click or tap to enter a date. |
| **\*If the person responsible has signed, please provide details below:**  **Name:** Click or tap here to enter text. **Date of Birth:** Click or tap to enter a date.  **Address:** Click or tap here to enter text. **Contact Number:** Click or tap here to enter text.  **Relationship to patient:** Click or tap here to enter text. **Reason for representation:** Click or tap here to enter text. |
| **If applicable, name & signature of witness:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** Click or tap to enter a 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**

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| 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:** Click here to enter text. **Designation:** Click here to enter text.  **Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:**Click or tap to enter a 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**: Click here to enter text. **Name of interpreter:** Click here to enter text.

**Employee ID:** Click or tap here to enter text.**Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:**Click or tap to enter a date.

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