**PRESCRIBER ACKNOWLEDGEMENT AND CONFIRMATION REGARDING PATIENT CONSENT**

TO BE COMPLETED BY THE TREATING MEDICAL SPECIALIST OR APPROPRIATE DELEGATE FOLLOWING DISCUSSION WITH THEIR PATIENT AND PROVIDED TO THE AUSTRALIAN RED CROSS BLOOD SERVICE

I acknowledge the governance and management arrangements for the appropriate supply and use of immunoglobulin products, funded under the national blood arrangements, and the provision of information required to support authorisation. **I have provided and/or explained to my patient (or parent/carer/guardian)** the Privacy Statement and Notice (Notice) and Patient Information Brochure and they have had the opportunity to ask questions.

**I believe that my patient (or parent/carer/guardian) is aware of and understand:**

* the risks and benefits of treatment with immunoglobulin products and alternative treatments (where these exist),
* the national access conditions and governing requirements for the appropriate supply and use of immunoglobulin products under the national blood arrangements, including that immunoglobulin products may need to change from time to time,
* (for patients requiring ongoing treatment only) the nature of ongoing monitoring and review and that access to product will cease if response to treatment does not demonstrate clinical benefit.

**I confirm that my patient (or parent/carer/guardian) has provided express consent (explicit oral or written consent) to:**

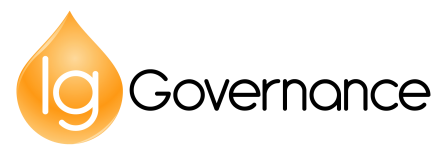
* the collection and recording of personal information (including sensitive health information) in secure databases, held by the Australian Red Cross Blood Service (Blood Service) and the National Blood Authority (NBA),
* the use of this information by clinicians to submit a request for, and for the assessment of, initial or ongoing authorisation for access to publicly funded immunoglobulin products, against the *Criteria for the clinical use of intravenous immunoglobulin in Australia Second Edition*[[1]](#footnote-1) determined by clinical experts and approved by Australian governments for this purpose,
* the use of limited identifying details (for example, name, date of birth, sex and hospital identifiers) within search functions of the above mentioned databases to ensure that patients are correctly identified,
* the disclosure to and use of this information by clinicians in Australian treatment facilities that they attend for health care, in order to deliver health services according to the purposes set out in the Notice, and
* the disclosure and use of this information in a manner which will not readily identify them, (such as through the removal of directly identifying personal information, or use of summary level grouped data) for the secondary purposes of: identifying priorities for research, prescriber education and training; performance evaluation and improvement of the supply, authorisation and use of immunoglobulin products; further developing the criteria upon which Government policy is based; supply planning so the NBA can make sure enough Ig products are available to meet patients’ needs; and enabling reporting on the program for supply, authorisation and use of publicly funded immunoglobulin products.

My patient understands that any additional use of information held by the Blood Service and NBA will only be undertaken in accordance with the requirements of the Privacy Act 1988 (Cth) and any relevant state/territory laws, and that the information may be made available for medical or public health research only with approval of a properly constituted human research ethics committee (HREC).

**I also confirm** (if applicable):

* my patient is suitable for self-administered treatment within a participating hospital (based SCIg program as specified on page 1 of this form), and
* the approved access conditions and governing requirements will be complied with through the hospital based SCIg program.

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| Patient Name: | Consultant/Treating Medical Specialist **(required):** | |  |
| MRN/URN: Date of Birth: | | | |
| Treating facility & address where clinically reviewed (required): | | Administering facility & address where Ig infused/given (required): | |
| Consenting Doctor’s Name: | | | |
| Signature: Date: | | | |



**PATIENT CONSENT**

TO BE COMPLETED BY THE PATIENT (OR PARENT/CARER/GUARDIAN) FOLLOWING DISCUSSION WITH THEIR PRESCRIBER AND PROVIDED TO THE AUSTRALIAN RED CROSS BLOOD SERVICE

**I am aware of and understand:**

* the risks and benefits of treatment with immunoglobulin products and alternative treatments (where these exist),
* the national access conditions and governing requirements for the appropriate supply and use of immunoglobulin products under the national blood arrangements, including that immunoglobulin products may need to change from time to time,
* (for patients requiring ongoing treatment only) the nature of ongoing monitoring and review and that access to product will cease if response to treatment does not demonstrate clinical benefit.

I have read and/or been explained the Privacy Statement and Notice (Notice) and Patient Information Brochure. I have had a chance to ask questions, and all my questions have been answered to my satisfaction. I understand and accept the Notice.

**I hereby provide express consent to:**

* the collection and recording of personal information (including sensitive health information) about me/my child/the person I care for or represent in databases held by the Australian Red Cross Blood Service (Blood Service) and the National Blood Authority (NBA),
* the use of this information by clinicians to submit a request for, and for the assessment of, initial or ongoing authorisation for access to publicly funded immunoglobulin products, against the *Criteria* *for the clinical use of intravenous immunoglobulin in Australia Second Edition[[2]](#footnote-2)* determined by clinical experts and approved by Australian governments for this purpose,
* the use of limited identifying details (for example, name, date of birth, sex and hospital identifiers) within database search functions to ensure that I can be correctly identified when required by my treating clinical team,
* the disclosure to and use of this information by clinicians in Australian treatment facilities that I attend for health care, in order to deliver health services according to the purposes set out in the Notice; and
* the use of this information in a manner which will not readily identify me (such as through the removal of directly identifying personal information, or use of summary level grouped data) for the secondary purposes of: identifying priorities for research, prescriber education and training; performance evaluation and improvement of the supply, authorisation and use of immunoglobulin products; further developing the criteria upon which Government policy is based; supply planning so the National Blood Authority can make sure enough Ig products are available to meet patients’ needs; and enabling reporting on the program for supply, authorisation and use of publicly funded immunoglobulin products.

I understand that any additional use of information held by the Blood Service and NBA will only be undertaken in accordance with the requirements of the *Privacy Act 1988* (Cth) and any relevant state/territory laws, and that the information may be made available for medical or public health research only with approval of a properly constituted human research ethics committee (HREC).

|  |  |  |  |
| --- | --- | --- | --- |
| Patient Name: | | Consultant/Treating Medical Specialist **(**required**):** |  |
| Parent/Carer/Guardian: | | | |
| Patient’s Date of Birth: MRN/URN: | | | |
| Treating facility & address where clinically reviewed (required): | Administering facility & address where Ig infused/given (required): | | |
| Signature: Date: | | | |
| Witness Name: | | | |
| Witness signature: Date: | | | |

1. *Criteria for the clinical use of intravenous immunoglobulin, Second Edition (July 2012)*, COAG Health Council ([www.blood.gov.au/ivig-criteria](http://www.blood.gov.au/ivig-criteria)).

   Form ID – NBA – 301008 Effective October 2015 [↑](#footnote-ref-1)
2. *Criteria for the clinical use of intravenous immunoglobulin, Second Edition (July 2012)*, COAG Health Council ([www.blood.gov.au/ivig-criteria](http://www.blood.gov.au/ivig-criteria)).

   Form ID – NBA – 301008 Effective October 2015 [↑](#footnote-ref-2)