REQUEST FROM TREATING CLINICIAN FOR EXCEPTIONAL RELEASE OF NON-CONFORMING PRODUCT

You have requested that the New Zealand Blood Service (NZBS) make a non-conforming product available to your patient. Before this product can be released to you for transfusion or transplantation to your patient, the NZBS requires you to read this form and to acknowledge full responsibility for the use and consequences of the use of the non-conforming product/s.

Non-conforming products have not completed all the required screening and manufacturing processes carried out by the NZBS or fail to meet a specification for the product. They are not permitted for use except in life threatening emergencies where alternative treatment options are unavailable or would be inadequate. It is your responsibility as the treating clinician to verify that such a condition exists.

Where possible, NZBS will complete all the required tests on the non-conforming product you are intending to use for your patient and will notify you if any of the tests give positive results.

Risks and treatment alternatives: An NZBS specialist will explain to you the risks associated with the product you have requested, and the alternative treatment options that may exist for your patient.

It is your responsibility to consider the risks and alternatives carefully when requesting and using non-conforming products.

Patient informed consent: You are responsible for explaining to your patient the risks associated with the treatment you are considering, and the alternatives that are available. You are responsible for obtaining all necessary consents, and to comply in every respect with the Code of Health and Disability Services Consumers' Rights 1996.

If you need assistance in explaining risks and alternatives, an NZBS Transfusion Specialist is available.

Terms and conditions: Non-conforming products are supplied by the NZBS only on special terms and conditions. Your hospital will be aware of these conditions. In requesting the supply of non-conforming products, you accept and become bound by those conditions.

SECTION ONE: TO BE COMPLETED BY TREATING CLINICIAN

NON-CONFORMING PRODUCT REQUESTED:

1. PRODUCT NAME: _____ **DONATION NO:** _____

2. CLINICAL REASON NON-CONFORMING PRODUCT IS REQUIRED: _____

_____

I have requested the use of non-conforming product/s for this patient. I have read this document and confirm that I have been advised and understand the risks associated with using non-conforming products. I have also been advised of, and have considered the alternative treatment options that are available for my patient.

I have explained (or will explain) the risks and alternatives to my patient. I acknowledge that obtaining all necessary consents (and otherwise complying with the Code of Health and Disability Consumers' Rights) is my responsibility alone.

I am aware of the terms and conditions on which the non-conforming products are supplied for use by NZBS and agree to be bound by them.

I understand that non-conforming products are supplied by the NZBS in life threatening situations only and confirm that to the best of my knowledge and belief such a situation exists for my patient.

Patient Name: _____ NHI No: _____

Date Required: _____

Clinician Name: _____ NZMC Registration number: _____

Signature: _____ Date: _____

NZBLOOD
Te Ratonga Toto O Aotearoa

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SECTION TWO: TO BE COMPLETED BY NZBS TRANSFUSION MEDICINE SPECIALIST

PRODUCT NON-CONFORMANCE: _____

☐ I have discussed the risks associated with the use of the non-conforming product with the treating clinician (*if applicable*)
☐ Not Applicable (Clinician is aware of the potential risk)
☐ I have discussed possible alternative treatments with the treating clinician (*if applicable*)

Non-conforming product approved for exceptional release: YES / NO*

Name: _____

Signature: _____ Date: _____

* Reason Exceptional Release is not Approved_____

SECTION THREE: TO BE COMPLETED BY LOCAL QUALITY SYSTEMS ASSOCIATE

If the request is after hours or during statutory holidays the QBP will review and sign the form at the earliest opportunity during office hours

Non-conforming product approved for exceptional release: YES / NO*

Name: _____

Signature: _____ Date: _____

* Reason Exceptional Release is not Approved_____

SECTION FOUR: TO BE COMPLETED BY NZBS TECHNICAL SERVICES STAFF (RMLS / RMLT)

If the request is after hours or during statutory holidays technical staff may release the product after authorisation from the TMS / MO and prior to the QBP having reviewed and signed.

Donation Number:		
Component Name:		
Component Released:	**Date:**	**Signature:**
Follow up of Non-Conformance *i.e. test results*	**Date:**	**Signature:**
Attach a copy of the completed results		
Forward to TMS / MO upon completion of all results: if results are reactive / positive forward to TMS / MO without delay*		

* There is no need to contact TMS / MO urgently if positive / reactive results were the reason for the exceptional release.
* As mandated for exceptional release please raise an incident report. *Refer to 111M019 for Requirements*

Incident Required? ☐ **Yes** **Incident Number:** _____
☐ **No**

SECTION FIVE: FINAL REVIEW TMS AND QBP

TMS Name:	
Signature:	**Date:**
QBP Name:	
Signature:	**Date:**