MANAGEMENT OF CLINICAL REQUESTS FOR NON-STANDARD BLOOD COMPONENTS

REASON FOR ISSUE: Changes made for Waikato Site Programme of Work: added section 6.2 production and delivery planning; TMS must communicate to all departments involved and organise a meeting upon receipt of requests for non-standard components, clarified at 7.1 that the relevant department Team Leader is responsible for communicating any issues arising within their department to the TMS to be relayed to the requesting clinician.

1. PURPOSE

To outline the processes that NZBS will adopt in response to requests from clinicians for non-standard blood components.

2. SCOPE

This policy covers all sites within NZBS that receive requests from clinicians for non-standard blood components.

3. KEY RESPONSIBILITIES

Transfusion Medicine Specialists and Medical Officers (TMS / MO) will prompt DHB clinicians to complete the necessary form to enable access to non-standard blood components.

TMSs and MOs will ensure that the clinician understands that the requested component is manufactured specifically to meet the clinical requirement and that it is not a Medsafe approved product.

DHB Clinicians will provide information using the appropriate NZBS form to ensure that NZBS is fully aware of the indication for a non-standard component and the essential characteristics that should be met when providing it.

NZBS Manufacturing sites will ensure that non-standard blood components are produced to the specification identified on the form and that necessary approvals are obtained prior to the component being released for clinical use.

4. DEFINITIONS

Non-Standard Blood Component – a blood component that is produced for a specific patient upon request by the treating clinician and whose production involves a level of customisation within the processing laboratory resulting in a component that does not meet Medsafe approved specifications. The component is therefore an unapproved blood component.

5. DOCUMENTS

5.1 Required Documents

- 111F053 Non-Standard Component Request and Record form
- 111F054 Request for a Non-Standard Component

6. PROCEDURE

6.1 Initiation of Request

6.1.1 Normally a DHB clinician will initiate the request for non-standard blood components for a patient. Requests must be directed to an NZBS TMS or their delegate and timeline expectations should be clarified at this time. Following initial discussion, the requesting clinician must complete 111F054 Request for a Non-Standard Component, which is accessible on the DHB Blood Resource Website via the DHB Intranet.

6.1.2 Upon receipt of the completed 111F054 from the requesting clinician the TMS / MO will complete the reverse side of the form (Office Use NZBS) and indicate whether the request is approved.

6.1.3 The TMS retains the original form and returns a copy to the requesting clinician.

6.1.4 For accepted requests the TMS completes section A of 111F053 Non-Standard Component Request and Record form which documents the processes within NZBS to identify a suitable donor and undertake the collection and processing of the donation.

6.2 Production and Delivery Planning

6.2.1 Upon receipt of 111F054, the TMS must inform the departments which will be involved in supplying the special component/s as relevant:

- Donor Relations
- Collections
- Blood Processing/CTL
- Donation Accreditation
- Logistics

6.2.2 For time sensitive components (e.g.: Concentrated Platelets, Buffy Coats for Transfusion) the TMS must organise a meeting involving representatives from each department involved to plan for collection, manufacturing, and delivery of the component/s.

6.2.3 Following appropriate communications, 111F053 and 111F054 should be forwarded to the local Blood Processing/CTL laboratory.

6.3 Review

6.3.1 Following manufacture of the non-standard component the Team Leader Blood Processing /CTL or delegate will review the manufacturing records to ensure that all requested criteria have been met.

6.3.2 The forms will then be forwarded to the TMS / MO for final review and sign-off on 111F053.

7. MANAGEMENT OF ISSUES

7.1 The relevant Team Leader is responsible for ensuring that any issues occurring during collection or production of the component are notified to the TMS / MO without delay.

7.2 The TMS / MO is responsible for notifying the requesting clinician of any issues arising during collection or manufacture that impact either on the ability to supply the component at the designated time / date and any non-conformances to the criteria requested in 111F054.