MANAGEMENT OF CLINICAL REQUESTS FOR NON-STANDARD BLOOD COMPONENTS

REASON FOR ISSUE: To clarify that non-standard components are not approved by Medsafe, DCR23411 to clarify that non-standard components are produced according to clinical need and are customised for a specific patient, DCR23602 removed Matched Platelets as these are a standard blood component and therefore this policy does not apply.

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 Normally a DHB clinician will initiate the request for non-standard blood components for a patient. These requests must be directed to an NZBS TMS or their delegate. 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.

6.2 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.

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

6.4 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. Forward both 111F053 and 111F054 to the local Blood Processing / NCDL laboratory.

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