

**THERAPEUTIC GOODS ORDER NO. XX - *Standards for minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapies***

Reviewer: Stephanie Beeton  
[Hunter New England Bone Bank]

Date 12/2/10

Clause Ref.	Page Ref.	Comment	
6 Exemptions	5	It is not clear if autologous skull flap donors are exempt.	
Schedule 2 (1)(b)(ii)	9	Is the concern only with blood transfusion here, or should there be reference to operations in these countries? And what about their partners?	
Schedule 3 (2)	10	Living donor is being discussed, and an interview with the donor OR guardian is mentioned. Due to the personal nature of the Lifestyle questions, current practice is to interview the potential donor in private, with no family members.	
Schedule 3 (2)(d)	10	For live donors it is mentioned that currency of the history must be confirmed in writing by the donor within 7 days prior to donation. Logistically, how is this to happen? Over the phone contact is possible and is currently practiced.	
Schedule 3 (3)(i) and (s)	11/12	Why is a tissue recipient deferred from becoming a donor, when donor tissue in Australia has such a good safety record due to the screening undertaken?	
Schedule 3 (3) t	12	Is this saying that provided the blood received met these requirements, then no exclusion is required?	
Schedule 4 (2)(b)	14	There needs to be more flexibility here, as even if blood is collected on the day of donation, clotting or lost samples can occur. There needs to be flexibility to collect even post collection of the tissue.	
Schedule 4 (10)	15	Refers to 180 day blood sample taken from live donors as being "180 days post donation." However, on Schedule 5 (1) a, it says "180 days after the initial blood sample is taken". Which is correct? Is the 180 day repeat blood testing on live donors from the day of tissue donation or from the day of initial blood testing, because they are often different.	
Schedule 5	16	Agree that provided initial and 180 day serological testing is attended on live donors then NAT is not	

(1)(a)		required.	
Schedule 5 (1)(c)	16	What type of physical examination and to what extent is this done on live surgical donors?	
Schedule 5 (2)(a)	17	Should syphilis be included here?	