DRAFT THERAPEUTIC GOODS ORDER - *Standards for minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapies*
Donor Tissue Bank of Victoria submission Feb 2010

Clause Ref.	Page Ref.	Comment	Rationale
4(2)	2	**Allogeneic** – does not include provisions for identical twin, hence description should state "from an individual other than the recipient"	Donation between identical twins is allogeneic
4(2)	4	**Physical examination** – should state "to identify risk factors" rather than "to determine suitability of the person to be a donor".	Physical assessment is only an element of donor suitability assessment.
4(2)	4	**Tissue** Add 'human' Although extracellular matrix is originally formed by cells, the definition may be a weak to capture this significant area.	Could inadvertently cover animal derived tissue (and human is specified in definitions elsewhere)
6	5	To be included as an exemption: "autologous tissued used in the same procedure"	Tissue can be taken from one site for transplant in the same procedure to another e.g. skin and bone graft. The requirements for testing etc should not apply as the tissue is not banked and only one patient is present in the theatre at the time.
Schedule 2			
1a)	9	*Schedule 1, table 1 –refers to "Autologous", "Compliance with requirements set out in schedule 2" is "All requirements except 1b)"* For autologous, 1a should also be an exclusion	Travel history irrelevant for autologous donors.
Schedule 3			
2	10	Remove face-to-face- requirement (or add the ability to undertake the interview and/or confirm information provided by phone)	There is no evidence that face to face interview is always better than for e.g. over the phone (a more experience interviewer via phone may be better than a less experience interviewer in the field)
2d)	10	This section needs review. The rationale for the 90 days and the 7 days prior to donation with update in the case of repeat tested donors needs to be justified. As an example, why is it not acceptable to update medical history <u>after</u> tissue donation and prior to release?	Unclear
Table 2	10	General comment – the period of ineligibility refers to 'prior to donation'. In the case of tissues should read before tissue release e.g. prior HBV.	For example, why cannot the donation occur, and then test the blood for Anti-HBS and if >100IU, then accept, discard if not?
Table 2 (k)	11	Autologous use is left blank, should this be "Nil"?	? Editorial comment
Table 2 (q)	12	"Risk of prion disease" is too vague, this needs to be more prescriptive e.g.	The rest of the table (which could equally

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		residency in UK, family history CJD etc.	be bundled together as risk of infectious disease) is prescriptive
Table 2 (s)	12	Recipient of allogeneic tissue should carry the same weight as recipient of blood (i.e. 12 month deferral). Organ recipients may be permanent rejection due to medical condition and anti-rejection therapy.	Why is a blood recipient satisfactory to donate, but recipient of tissue allograft is excluded as a donor (from a deceased donor there may well be more information regarding safety than from a living donor e.g. autopsy report for silent disease)? It will be difficult to differentiate from a patient whether a tissue graft was from a living or deceased donor unless by chance the bank had supplied the tissue.
Schedule 4			
2b	14	As close as practicable to the time of cell or tissue collection (remove reference to prior)	Blood can be collected after donation or a second sample could be obtained if the 1st sample is rejected e.g. leaking tube / lysis etc.
11	15	Change “possible and practicable”, to “undertake a risk assessment…”	The risk of introducing a new test could be negligible (e.g. HLTV where the incidence in Australia is extremely low) and hence the logistics of testing the inventory extensive for minimal benefit. It also assumes the new test is better than the prior test (e.g. the better test could no longer be available or approved for use).
13	15	Remove initial reactive result clause	If the repeat test is non-reactive then the donor status (in terms of serology) is negative. Reporting an initial reactive serves no purpose (if fact could cause confusion and inappropriate reactions) and goes against the manufacturers insert reporting instructions.
Schedule 5			
1c)	16	Physical examination only for deceased donors.	Physical examination is not practicable for living tissue donors e.g. intrusive genital exam or full body surface examination for moles.

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2	16	Reword 1st sentence – it is not clear which sample the NAAT testing refers to and whether this needs to be repeated. Suggest: All tissues and cells should be tested by serology on the donation sample (see Table 4). Where cells and tissues can be stored for long periods without impairing fitness for use, the donor should be repeat sampled >180 days post donation by serology for HIV, HBV and HCV to ensure the index sample was not collected during the window period of infection. Where cells and tissues cannot be stored for long periods, NAAT testing for HIV, HCV, and HBV (when available) should be performed on the donation sample to reduce the window period of infection.	If 180 day serology is performed NAAT serves no purpose. It is reasonable to require NAAT testing to reduce seroconversion window period where 180 day repeat serology is not possible,
3	17	Suggest 1st paragraph just state 'for autologous donors:'	Editing to simplify
5b)	17	Schedule 1, Table 1 excludes this requirement for skin; however should say "allow release of skin with viable count except when organism is of clinical significance"	The rest of section 5b is relevant for skin donation.