Comment on Draft Infectious Diseases Standard

To:

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On behalf of the Centre for Blood Cell Therapies at the Peter MacCallum Cancer Centre we thank you for the opportunity to review this document.

We are very pleased with the concept but have the following comments to make.

General comments

We note that this document has a very sound intent and purpose but in its current form is virtually incomprehensible.

We have reviewed it only within the scope of our current licensed activities – that is autologous products such as HPC-A, and tissue products covered by Autologous – Other Products.

Schedule 1 has obvious errors when it is compared to Table 4 which in our opinion is a much more understandable guideline.

There seems to be a curious discrimination between HPC-A and other tissue products where we feel that a 30 day rule is a reasonable uniform approach to the maximum interval for assessment and testing (as opposed to 30 days for one and 7 days for the other).

Most disturbingly is the presumed error in Table 1 which specifies repeat 180 day testing for autologous tissue which is not required for HPC-A. Table 4 hopefully is the accurate representation of TGA's intent in this matter.

Section	Page	Clause and Comment
4 (2)		*allogeneic means material for administration to an individual that is obtained, or derived, from a genetically different individual;* *autologous means material that is obtained, or derived from, an individual for administration to the same individual;* This section should include the definition for 'syngeneic'. Note: Remaining sections of standard may need to modified in line with the definition. This has not been addressed in these comments
Schedule 1	6	This schedule contains numerous errors and inconsistencies compared to the much more clearly set out Table 4.
Schedule 2 (1)(a)	9	Clause (1)(a) is broader than (1)(b), therefore exclude or broaden it to include a risk-benefit analysis so that if 1(b) is excluded the same risk benefit analysis also applies to 1(a) if this is the only applicable clause.
Schedule 2 (1)(a)	9	Why is (1)(a) not exempt for autologous product when (1)(b) no longer applies. Thus if UK residency is not seen as a risk for autologous product why would other regions matter? The implication is that every autologous donor will have travelled outside of Australia within the last 3 years and this results in a significant amount of redundant effort.
Schedule 3 (2)(a) & (b)	10	For autologous tissue product, the interview must be no more than 7 days prior to donation, but for HPC-A or HPC-M there is a 30 day period. What is the basis for the different period? Why not 30 days for all, there seems to be no logical justification for this requirement.

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Schedule 3 (4)	12	Autologous products (HPC-A, HPC-M, other products) are exempt from (3) – thus the social criteria specified in table 2, **unless** (as per clause 4) the donor is less than 18 months, in which case their mother has to provide a social history. This is inconsistent. If the mother would not be required to do this in her own right as an autologous donor why should she have to do this if her infant was an autologous donor. Thus HPC-A, HPC-M, other products should be also exempt from Clause (4) as shown Table 1.
Schedule 3 (1) & Table 2	10	Table 2 specifies periods of ineligibility for allogeneic donors, but for autologous donors the period of ineligibility is 'nil' for all criteria. It is hard to follow whether this is a double negative or whether not applicable is meant. Is there an implied expectation that product from a donor answering 'yes' to any of these criteria will be segregated in some way?
Schedule 4 (2)(b) & (d)	14	For tissue donors (other products), the interview must be no more than 7 days prior to donation, but for HPC-A or HPC-M there is a 30 day period. What is the basis for the different period? Why not 30 days for all donors/products?
Schedule 5	8	As shown in **Schedule 1, Table 1** - Donor Group 4. Living Donor- Autologous - Other Products, Compliance with requirements set out in schedule 5 ,Table 1 specifies Schedule 5 exemptions: All requirements except subparagraph (1)(c)(iii) and paragraph, (1)(d) It appears as if "**and clause (2)**" has been omitted from this section. Adding this phrase would make it consistent with the requirements shown in Table 4 for 180 day serology / NAT retesting. This is a very significant error as it would result in the unjustifiable practice of retesting autologous tissue donors at 180 days. We hope that the intent is what is shown in Table 4 which indicates that such tissues would not require 180 day testing if they are autologous.
Schedule 6 (1)	19	*Critical materials employed in the processing of human blood, blood components, human tissues or human cellular therapies must be selected and **evaluated** to ensure they are not contaminated with or likely to introduce pathogenic bacteria or other infectious agents to the human blood, blood components, human tissues or cellular therapy.* Does 'evaluated' mean 'tested'? This general intent of this statement seem out of place and would be better placed within a code of GMP which covers this requirement much more effectively.