Submission on TGA consultation: Proposed standards for human blood and blood components, human tissues and human cellular therapy products

Organisation: VIFM t/a Donor Tissue Bank of Victoria

Thank you for providing your comments using the template below.

- Rows may be added or deleted as required. Tables may be left blank or deleted if no comments are to be made on other documents.
- 'Reference' indicates the specific section/ subsection/ paragraph where relevant, e.g. In the infectious disease Order, 8(1)(b) would be used to reference requirements for donor interview timeframe in Part 3, Section 8, Subsection (1), paragraph (b).
- 'Issue' invites a short statement to summarise the comment.
- 'Comments' may include a position including justification or an alternative position.
- Additional general comments are also invited on the impact of these standards, as indicated below each table.

Standards for minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products

SUBMITTING ORGANISATION: VIFM t/a Donor Tissue Bank of Victoria

Reference	Issue	Comment
6. (3)(b)	add "applicable for **autologous use** only"	There is room for interpretation that unregulated banking for allo-donation can take place.
6.(3)(c)	add "applicable for **autologous use** only"	There is room for interpretation that unregulated banking for allo-donation can take place.
8.(1)(a)	remove to 'face-to-face' interview requirement.	There are circumstances where a telephone interview is appropriate e.g. the donor guardian and/or next of kin representing the donor due to age or consciousness will not be available for face-to-face interview within timeframes for donation eg. NOK abroad. More specific follow up issues on the medical history may also be followed up with the donor by the tissue bank by telephone after donation to clarify statements made prior to donation. Mandating face to face interview will preclude donation unnecessarily. A well performed phone interview is no greater risk than a well performed face to face interview.
8.(1)(b)	Change to include "The interview must occur no more than **30 days prior or after collection"**	The value of the interview only 7-days prior is limiting for living donors. Quite often, potential donors are interviewed at pre-admission clinics which are undertaken 2-3 weeks pre surgery (donation). If surgery is postponed, a repeat interview is likely to be required with little or no benefit to reducing the risk of capturing additional exclusion information.
8.(2)	Remove 'where possible' and the option "and/or"	There must always be an interview with the NOK/guardian of a deceased donor AND examination of the medical documentation in order to establish sufficient information.
8.(2)	a) change:"examination of the medical	There are instances where medical information may take more than 7 days following donation to be accessed and reviewed. Without the change, this

	documentation to obtain and record the medical and social history of the donor must take place and be recorded at the time of, or no more than 7 days prior to or following collection" to: "examination of the medical documentation to obtain and record the medical and social history of the donor must be initiated and be recorded at the time of, or no more than 7 days prior to collection**. This must be completed before release of tissues from quarantine**	requirement will cause the discard of likely safe tissue.
Table 1; (h)	Remove 'deceased'	The requirements should be the same for both living and deceased donors
Table 1; (j)	Needs rewording	It is not necessarily the donor's sexual practices that is the issue but with whom he/she entertains the practice (i.e. MSM and prostitutes). Eliciting a donor's sexual practices may be inappropriate the way the criteria is worded e.g. a risk associated with MSM is anal intercourse, hence the clause would suggest eliciting from a donor whether he/she entertained (amongst other more risky sexual practices) anal sex (either hetero or homosexual) – although it could be argued this is indeed a risk that should be excluded. It is however proposed this line of explicit questioning could be deemed by the donor population to be inappropriate.
Table 1; (o)	6 month ineligibility is too	This is too radical for living tissue donors. Consider: review of donor status 06

	restrictive	months post visit in terms of symptoms and/or possible release of irradiated tissues where the dose would kill the parasite.
8.(6)	Include possibility of baby donor receiving milk from a Milk Bank; whereby the milk donor may need to be evaluated.	
8.(11)(b)	suggested to remove "from the scientific literature"	This considering that quite a number of "tissue banking" processes have been established through "judgement and practice" rather than "documented science".
9.(8)	Suggest adding "..taken from living donors at 180 days **minimum** post collection	This will allow for over 180 days.
10.(4)(d)	Address feeding from Milk Bank and milk donor screening.	This requirement does not clearly capture babies that may have had donated milk
11.(3)(c)	? change -40˚C to -80˚C	Query whether temperature for cryoprotected should not be stated as -70oC as purpose of practice is for longer term storage and hence need for lower temp.

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments:

Standards for human cardiovascular tissue

SUBMITTING ORGANISATION: VIFM t/a Donor Tissue Bank of Victoria

Reference	Issue	Comment
4. *minimal manipulation* (f)any similar thing to a thing mentioned in paragraph (a),(b),(c),(d) or (e)	Suggested to include tissues processed in high **concentration of glycerol** (i.e. >75%) – e.g. vascular conduits	
7.(2)(a)	– suggested change from : "transported at 2°C to 8°C to the… To : "transported refrigerated (2°C to 8°C) or in wet ice (0°C-8°C) to the…	The lower limit is to prevent ice crystal formation as a result of dropping below 0°C. For mechanical refrigeration to allow for equipment function, variation and response time to failure, therefore the lower limit is usually set at 2°C. Wet ice (without refrigeration) cannot drop below 0°C, therefore the limit of 0°C with wet ice is acceptable, and is the option/preferred method of transportation e.g. organs packed in wet ice for transplant.
7.(2)(a)(i) and (ii)	Suggested increase timeframe from 30 to 36 hours (i.e. 12 hours for transport until manufacture)	The time frame of 30 hours is challenged as this may preclude transfer of tissues collected at 24 hours across the country (e.g. heart blocks from Tasmania retrieved at 24 hours asystole needing to be transported interstate).
7.(2) (d)	Suggest adding 'Final' to '..samples must demonstrate no growth'	Samples prior to decontamination may have non pathogenic flora present that are removed as a result of the bioburden reduction process which may be acceptable for release.
7. (10)	Additional text…"to be	Short term storage at -80°C and transport on dry ice is accepted international practice.

	transported at or below minus 100oC, or in dry ice (-80oC) in a validated container system."	

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments:

Standards for human musculoskeletal tissue

SUBMITTING ORGANISATION: VIFM t/a Donor Tissue Bank of Victoria

Reference	Issue	Comment
4. *minimal manipulation* (f)any similar thing to a thing mentioned in paragraph (a),(b),(c),(d) or (e)	Suggested to include tissues processed in high **concentration of glycerol** (i.e. >75%) – e.g. fascia	
6.(1)	Suggest to add "autologous tissue to be used in the same procedure"	An autologous graft used in the same surgical procedure e.g. iliac crest from the patient used as graft for a knee revision or tendon for a knee ligament reconstruction in the same surgical procedure (i.e. not temporarily stored) should be exempt.
6.(1)(c)	Tissues processed beyond minimal manipulation not included in this order	Query if appropriate to exempt from order "tissue that is processed beyond minimal manipulation. Such tissue start materials still need to comply to this order + further processes to have distribution approved (e,g dossier)
7.(2)(b)	Addition "…bioburden determination **when no further processing is to be undertaken prior to release"**	Samples taken at retrieval of tissue that is processed prior to release are of less value to final product release determination. The information from this can be used as a potential early indicator for discard. The most important sample for release purposes is the final sample taken prior to final packaging of the tissue.
7.(3)	Addition "…..bioburden reduction process must demonstrate no	See above

	microbial growth when ***final prepackaging*** representative samples are tested."	
7.(6)(c)	Suggest to change from "…representative samples of musculoskeletal tissue must have…" to: "…samples representing the musculoskeletal tissue must have…"	These samples tested may be fluids (bathing solutions), which are also indicative of the tissue environment.

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments:

Standards for human ocular tissue

SUBMITTING ORGANISATION: _____

Reference	Issue	Comment
	No information regarding transport temp of tissues	There are no requirements for transport temperatures when tissues are transported between collection and transfer to processing Bank; and/or from Bank to end-user as in other Orders.
6.(1)(d)	Amniotic membrane used for therapeutic ocular procedures	This is not included in any of the TGO's. Where does it fit?

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments:

Standards for human skin

SUBMITTING ORGANISATION: VIFM t/a Donor Tissue Bank of Victoria

Reference	Issue	Comment
4. *minimal manipulation* (f)any similar thing to a thing mentioned in paragraph (a),(b),(c),(d) or (e)	Suggested to include tissues processed in high **concentration of glycerol** (i.e. >75%) –	
6.(1)	Suggest include 'skin grafts for autologous use used in the same surgical procedure'	It is commonplace for split thickness skin to be taken from e.g. the patient's thigh to be used on the patient's burnt hand in a single procedure (i.e. not stored). These should be exempt.
6.(1)(c)	Human skin processed beyond minimal manipulation should not be exempt	Why include this as exemption as must comply with Order + additional dossier?
7.(10)(a)	Storage temperatures	Consider review . Usually (international practice) temperature is below -100˚C to secure 5 years and/or -80˚Cto-100˚C for 06 months

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments:

General requirements for the labelling of biologicals

SUBMITTING ORGANISATION: VIFM t/a Donor Tissue bank of Victoria

Reference	Issue	Comment
4	Definition of container as 'immediately covering the goods'	Immediately covering suggests the container that is in immediate contact with the tissue (according to the TGAct definition). Tissues are usually double (or triple) 'wrapped' with the label (not sterile) on the outer wrap. In inner most wrap cannot be easily labelled as the label would need to be sterile. It is presumed (although not clear) that the 'immediately covering' could be interpreted as the 2nd or 3rd level of sealed 'wrapping'. An exclusive (from Act) definition may be required.
6. (3) (c) and (d)	Date and time of collection and collection facility on the container – change to 'if applicable'.	Date and time of collection plus collection facility is usually recorded on accompanying paperwork (which is linked with the donor identifier). Additional labelling of the container adds time to the process and does not provide greater assurances than currently provided on the paperwork.

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments: