DRAFT TGO – standards for minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapies

PAGE	CLAUSE	COMMENTS
3	Interpretation	***banked*** – should include any tissue/cellular material retrieved for purpose of transplantation – whether or not it is cleared for use. ***bioburden*** Does "*the goods*" mean product or materials or both? I suggest specifying what is meant.
4 16	Interpretation Schedule 5 (c)	***Physical examination*** *means a clinical based inspection of a living or deceased potential donor to determine suitability of the person to be a donor and includes at minimum the relevance of any abrasion/laceration, bruise/haematoma, fracture, tattoo, piercing, scars, skin lesion, surgical incision or other distinguishing external feature that may be indicative of a behaviour, lifestyle or disease.* No issue with cadaveric donors – currently performed. However are live potential donors also to be subjected to a physical examination which would meet the minimum features listed in the definition? When I go to donate blood will I need to strip completely and be fully examined? Will a patient undergoing hip replacement surgery have to be stripped and fully examined by the surgeon prior to commencing the operation? Orthopaedic surgeons will not undertake this task. What is the definition of a "competent person" for conducting a physical examination (in particular reference to cadaveric donors)? What would be the minimum training/education background for this 'clinical based inspection'?
5 & 6	Exemptions	Tissues for direct transplant should be included. Excluding tissues for direct transplant will prevent this treatment being available. Currently this is not performed, but allowance should be made for future developments.
9	Schedule 2 Policy	*The manufacturer must have the following policies in place* The dialogue following this statement identifies requirements to be met that can be addressed through methods other than policies. I suggest "*The manufacturer must have a policy/ policies or procedures in place to address the following."*
10	Schedule 3 Table 2	Table 2 should follow (1)

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10	Schedule 3 (2) (a) and (d)	*(2) Human blood and blood components, human tissues or human cells must not be collected from a living donor unless the Medical and Social History interview has been conducted by a qualified interviewer at a face-to-face interview with the donor or guardian/next-of-kin.* *(a) the interview must occur as close as possible to, but at no more than 7 days prior to donation, unless (b), (c) or (d) applies, and the history must be documented at that time.* *(d) For cells and tissues, if repeat serological testing will be performed on donor blood samples collected at a minimum of 180 days after the initial sampling in accordance with Schedule 5 Item 2(a) then the interview must occur within 90 days prior to donation and currency of the history confirmed in writing by the donor within 7 days prior to donation.* Why must the face-to-face interview occur prior to donation? Completion of a face-to-face interview 7 days post donation is no less comprehensive and provides no less degree of safety than one conducted prior. The real risk here is that there will be fewer eligible donors because patients often do not have time prior to surgery to fit in this interview and patients are stressed and more likely to forget critical information. Post donation they do have the time for the interview. Allowing the face-to-face interview post donation, provided comprehensive documentation of verbal history has been undertaken prior to donation, should be acceptable. This process belongs within each banks operations process.
10	Schedule 3 (3)	Is '7 days prior' a cut and paste error? Why allow up to 7 days prior to retrieval for interviewing the next of kin? It is not permitted to retrieve 7 days after death. '7 days prior' could apply if the donor is being ventilated if the next of kin have requested this. We exclude if the donor has been ventilated for >72 hours.
10 & 11	Table 2 (a) & (c)	Why is ear piercing performed at a pharmacy using sterile, single use equipment excluded for 6 months when a needle stick injury is only excluded if 'thought to be at high risk"? Why is there a caveat on the risk of a needle stick injury?
12	Table 2	Period of ineligibility prior to donation for Allogeneic use (Permanent) *(s) Being a recipient of allogeneic organs(s) or cells, or deceased donor tissue allograft.* Why are cadaveric allografts considered to be a higher risk than allografts and blood from living donors? All of these items are regulated and scrutinised under the same system. Cadaveric donors have a post-mortem and NAAT testing. No exclusion period has been applied to recipients of MS allografts sourced from living donors. The risk from a tissue allograft would be the same if the donor was deceased or living. I suggest 6 months exclusion for recipients of allogeneic human tissue and cellular transplants where sourced & transplanted in Australia. Permanent could apply if the allografts were sourced o/seas.

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12	Table 2 (t)	Does this mean that 12 months is required when the blood was sourced o/seas and no exclusion when the blood was sourced in Australia?
12	Schedule 3 (5) (a)	Statement (5) covers tissues & cells, but (a) and Table 3 identifies only potential **tissue** donors – does this mean that they can donate cells? Information in statements & tables needs to be standardised.
14	Schedule 4 (2)	For a living femoral head donor, what is the risk if the blood testing period is extended to 180 days post donation provided the donation remains unopened until the blood test results have been received? The mandatory results should be for the 180 days test and banks should not have to destroy donations because the donation test was not performed.
14	Schedule 4 (3)	This needs to be reworded as it suggests that a pre-mortem blood sample has to be used if it is available which has the potential to delay testing if the post-mortem sample is suitable. Suggest "*Blood sampling of a deceased donor must take place prior to cell or tissue collection and no later than 24 hours after death. A pre-mortem blood sample collected up to seven (7) days prior to donation may be used if available.*
14	Schedule 4 (6a)	Sometimes "current" technology is not the most appropriate (eg. NAT vs 180 day retesting). (a) suggest "*most appropriate technology /methodology*".
14 & 15	Schedule 4 6), (7), (8), (9), (10), (12)	These clauses require the graft manufacturers to ensure that testing laboratories fulfil the requirements of their (laboratories) TGA licences. Manufacturers should only be required to ensure testing is conducted by an appropriately licensed laboratory (e.g. TGA/NATA). They should not be required to ensure these laboratories meet the requirements of their license. That is the responsibility of the licensing body. If the licensing body does not approve of the testing being conducted, the deficiency should be applied to the testing laboratory to address, not the manufacturer. Clause (8) – Does 'regulatory requirement' mean NATA labs without TGA licenses are allowed or does it mean the labs must be TGA licensed. Clause (9) and (10) seem to say the same with (10) providing more details. Clause (10) - why must the samples collected at the time of donation be archived when samples are collected at 180 days and these are archived. The donation samples should be able to be destroyed when the 180 days samples are archived. 'Minimum of 2 years' is not the same as 'the time of transfusion or implantation…' as stated in (8). Which period is required? In the previous Code, archive or retention samples had to be stored at -15°C or below (839) – the requirement is now -25°C. Does this mean that we would have to discard all samples currently archived if they have not been stored at -25°C or colder?

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16	Schedule 5 (2)	Why would you allow the choice between antibody / antigen testing and NAAT for a donor 180 days post donation? The value of NAAT is for window periods. At 180 days post donation, assuming the donor was infected at the time of donation, antibody / antigen testing is more efficacious.
16 / Schedule 5		(c) Refer to the previous (2nd) comment regarding physical examination. This is relevant for a cadaveric donor. Living donors will be affronted by this - it is rude. Who will the competent person be? Surgeon/Registrar on day of surgery – should this not be covered by a general 'fitness for surgery'?
18	Table 4	As HTLV is extremely rare, the probability of finding a positive donor is highly unlikely. (2 per 6,500 donors since 1999 at PBTB). Hence HTLV testing at the 180 days retest should be permitted as an alternative to testing at time of donation provided the donation remains unopened until the 180 days blood test results are received.
19	Schedule 6 (2) (b)	*…….. If the product is not required to be on the ARTG, the recorded information must include…….* Inconsistent (inappropriate) use of "product". Product should be reserved for what bank produces e.g. allografts or autographs. Should be "If these starting materials…….".