

Submission from XXXXXX

Re: Standards for banked human musculoskeletal tissue

Point 4 “Interpretation”

- ***allogeneic*** means material for administration to an individual that is obtained, or derived, from a genetically different individual

XXXXXX Comment: This definition does not include provisions for identical twin, hence description should state “from an individual other than the recipient” in preference to “genetically different individual”.

- ***banked*** means maintenance, under appropriate controlled conditions, in an inventory, of a finished product that has been determined suitable for supply;

XXXXXX Comment: Donated bone in bone banks is quarantined under appropriate controlled conditions for over 6 months **prior** to being a finished product ie determined “suitable to supply”. Does this definition therefore mean that such bone will not be considered to be “Banked”? The term banked should include any tissue/cellular material retrieved for purpose of transplantation – whether or not it is cleared for use.

- ***donor*** means every source, whether living or deceased, of blood, cells or tissues

XXXXXX Comment: “every *human* source” would be preferable to “every source”

7 General Requirements:

7 3 b iii

XXXXXX Comment: What grade/s of insitu carcinoma of the uterine cervix would be considered to be acceptable?

Additional comments:

The XXXXXX (XXXXXX) participated in the Australian Tissue Biotherapeutics Forum (ATBF) workshop to discuss the ATBF response to the draft code and standards.

The XXXXXX supports the ATBF submission to the TGA.