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Dear Sir/Madam

**RE: Code of GMP for human blood and blood components, human tissues and human cellular therapies - 5 new standards**

## Submission

I write as the Director of the Queensland Bone Bank and as the Scientific Secretary of the Australian Orthopaedic Association. I write in response to the draft revision to the Code of GMP published for stakeholder comment on 7 December 2009.

My comments come in two forms.

### *(a) Generic comments*

I am familiar with the submission forwarded by the Australian Tissue Banking Forum. It is dated February 2010. Comments have been made on all relevant components of the code as they pertain to the banking of human tissues. I support all the comments made by the ATBF.

### *(b) Specific comments*

I write specifically about Schedule 3 - (Medical and Social History) - Section (2). Section (2) states "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.

In analysing why TGA has inserted this particular caveat in the draft code, I assume that there are two specific reasons.

1. The first reason presumably is to confirm the identity of the donor providing the information.
2. The second reason presumably relates to the confirmation of accuracy of information being provided by the donor.

### Consider Reason 1

Given that the interview will not have had prior knowledge of the donor, the interview will rely upon documentary evidence provided at the time of the interview.

I am of the view that this can be accomplished without a face-to-face meeting. Instead, a telephone interviewer could ask a list of specific questions which would confirm the identity of the donor. These questions could be as follows:

- Full name
- Date of Birth
- Name of the Surgeon performing the operative procedure
- Date upon which the index surgery was performed
- Donors address
- Whether it was a right or left sided operation which was performed
- The hospital in which the procedure was performed

I find it extremely unlikely that any particular individual would pretend to be a donor. Even more unlikely would a pretend interviewee be aware of all the information listed above. It should be appreciated that the donor does not profit from the donation itself. It would be difficult to envisage a motive for not being truthful.

### Consider Reason 2

Is TGA suggesting that the interviewer shall possess some special expertise which could differentiate between fact and fiction when eliciting the specific interview details from the donor during the course of the face-to-face interview? If so, how does TGA quantify this special capacity, how is the capacity assessed and how can it be validated?

### Is there a problem?

This proposal to mandate face-to-face interviews does generate some specific problems.

From the Queensland Bone Bank perspective, we are currently gathering approximately 2500 femoral heads annually from 50 different hospitals spread over a surface area of 1.5 million km<sup>2</sup>. It would be extremely difficult to ensure that every donor interview was conducted in a face-to-face manner by an accredited interviewer.

It should be understood that every femoral head obtained from a donor is subjected to an exhaustive regimen of testing and processing before release to a recipient. Those tests include but are not limited to:

- A telephone interview with the Medical Officer searching for details of past medical history where indicated

- Exhaustive serological testing
- Exhaustive microbiological testing
- Exhaustive histopathological testing
- A 180 day retest after the donation
- Exhaustive processing
- Subjecting the allograft segment to 11kGray of gamma irradiation from a Cobalt 60/60 source.

Whilst the interview with the donor is not insignificant, its relative significance should be viewed in association with the other mandated tests.

#### Costs of compliance

In the event that the Queensland Bone Bank was forced to comply with this edict of a face-to-face interview with the donor, the following events would follow:

##### *Discard*

One thousand femoral heads, currently held by the Queensland Bone Bank, obtained with telephone interviews of the donor, would be discarded. These femoral heads have a production cost of \$1500.00 each.

##### *Training interviewers*

It would be necessary to enlist clinical nurses or the equivalent to perform these face-to-face interviews in the geographic regions from where femoral heads are currently retrieved. This would involve training the nurses in the intricacies of tissue banking and the requirements of an interview and then certifying the competency of these interviewers. These are interviewers who would currently replace our highly skilled and equally well trained donor liaison officers within the Queensland Bone Bank itself. At the very minimum, this process would take 3 months.

##### *Subsequent delay*

The collection of further femoral heads could therefore not start for at least 3 months. Every femoral head is thereafter subjected to a 6 month period in quarantine before the 180 day retests are performed.

##### *Effect on Australian patients*

It would therefore mean that there would be a minimum of 9 months before the Queensland Bone Bank could supply femoral heads. This would be approximately 1500 femoral heads absent from the community added to the already 1000 femoral heads described above which would be discarded.

It is probable therefore that as many as 1500 patients would be adversely affected by this single specific edict.

*Recommendation*

I would recommend that Schedule 3, Section (2), should be modified. Instead of the phrase "at a face-to-face interview" the section could read "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 with the donor or guardian/next of kin".

Yours faithfully

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cc. Dr John Quinn  
Executive Director for Surgical Affairs  
Royal Australasian College of Surgeons

Mr Ian Burgess  
Chief Executive Officer  
Australian Orthopaedic Association

Professor Loraine Holly

Professor Ming Zheng