Blood and Tissues Unit
Standards and Code of GMP
Office of Devices Blood and Tissues
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606 12.2.2010

Re Submission on Therapeutic Goods Order No. XX : "Standards for minimizing infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapies"

Thank you for giving the RACS an opportunity to comment on this document.

Overall the document seems quite acceptable and we have no major criticisms or concerns.

Two points need clarifying: firstly in schedule 3 what is meant by a "qualified interviewer"? Does this necessarily mean a Medical Officer, a registered Nurse or someone trained in tissue donation?

Secondly in the same section, paragraph 2(d) the requirement of confirming in writing the currency of the history by the donor within 7 days of the donation, after the donor has already provided consent and when the donor is to be retested at 180 days seems superfluous and with regard to live femoral head donations (from patients undergoing Total Hip Replacements) may be practically difficult to undertake.

I accept these 2 comments are minor concerns in an otherwise excellent document.

Yours Sincerely

Simon Williams

Chair Prevention of Hospital Acquired Infection Committee

Royal Australasian College of Surgeons