

## **January 2008**

Restrictions on the use of human tissue for research are impacting more and more on the renal research community. The regulations have been somewhat confusing as the interpretation of law that governs it, The Human Tissue Act 2004, has been evolving along with the whole process. The Human Tissue Authority (HTA) has been endeavouring to work with the scientific community in the development of workable processes and procedures. In fact, it is the questions from the end users which have prompted them to address the practicalities of certain scenarios. The Confederation of Cancer Biobanks recently held a workshop on quality processes for the collection of human tissue and samples during which a number of issues were discussed, serving to highlight the individualities of the whole process. Christiane Niederlaender was present as the representative from the HTA and gave an enlightening talk about where we are now. Below are some of the take-home messages.

The HTA comprises four directorates; regulations, communications, resources and policy. They are the only body who can licence the removal, procurement, processing, testing, storage, distribution and import/export of human tissues. They are currently developing a code of practice for the research community which will provide guidelines in this specific environment. These will hopefully be available late 2008. The process is based on risk, where high risk environments have been inspected as a priority. The research community has been seen as low risk up to this point and only four have been visited. This is now starting to change and many of us have dates when they are being inspected. They will be looking at four main areas; consent, Governance/quality systems, premises/facilities/equipment and disposal. The processes must show traceability, quality management and appropriate storage which is regularly monitored and has contingency plans for failures. Disposal of tissue varies as to the source from which it was obtained, i.e. tissue from the deceased has to be destroyed in a dignified manner separate from normal clinical waste.

Q - when do we need to ensure that a licence is in place? You do not need to worry about this while you are using tissue from the living for an ethically approved project and the ethics are still current, or you have reapplied and the decision is pending. As soon as the ethics runs out (and you haven't reapplied) the tissue needs to be included under a licence in a Biobank. The HTA will not allow any sort of short-term storage at all. Acceptance of your tissue into your local Biobank will depend on their criteria but mostly they will be looking for proof of consent, maintenance of the integrity of your samples and anonymised traceability. As soon as you obtain new ethics you can retrieve the samples. The HTA will not recognise any ethical approval other than that from NRES, i.e. not from a University ethics committee.

Q – what is covered by the licence? All tissue that contains cells whether viable or not. As well as the obvious this includes waste products such as urine and faeces, CSF and ascites. What is not covered is plasma, sera, GM cells, DNA/RNA/protein/lipid/carbohydrates, hair/nails from the living and cell lines that have been grown in culture within 48h of removal (unless for transplantation back into the patient).

Q – what about tissues taken for diagnosis? The tissue left over from diagnosis is often retained in an archive and described as surplus. As long as diagnosis was its primary purpose for removal it is fine to retain this in the clinical labs. If this tissue is then given out for research purposes it can only go to someone who has gained ethical approval or into a Biobank under licence. Tissue from the diagnostic archive can be used for auditing purposes but the findings cannot be published.

Q – who can hold a licence? Having a licence is quite an expensive process and therefore is left to Institutions such as Universities, Hospitals and Biorepositories, these then hold the legal responsibility. Each site will provide a designated individual who oversees the process and is an expert within that field. They ensure that other people involved are suitable to carry out their purpose and that the appropriate practices are in place.

Q – where can I go to for help? The HTA have a help section where you can send them questions and try to answer them within three weeks. They are very willing to work with you to sort out any problems that you may have.

Hope this is helpful for you.

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