Human Tissue Authority
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Date 09 June 2008

Professor M.A. Birchall.
Visiting Professor of Clinical Science at South Bristol,
Level 6,
UBHT Education Centre,
Upper Maudlin Street,
BRISTOL BS2 8AE

Dear Professor Birchall,

Re: Establishment of epithelial cell lines for autologous human application without an HTA licence

I have been in discussion with [redacted] about the above matter.

My understanding is that a seriously ill patient (with oesophageal carcinoma) at the Clinic Barcelona in Spain has consented for some of their normal tissue to be removed ('procured'). This material has been shipped to Langford, near Bristol, for the establishment of epithelial cell lines ('processing'). I presume these cell lines are also being stored at Langford for >48 hours (this would then constitute 'storage'). A clinician from Barcelona will soon come over to Langford to receive the cultures and take them back to Barcelona to treat the patient in what could be a life-saving operation.

My understanding is that you have now established that your samples are not classified as Medicinal Products or Investigative Medicinal Products, both of which would come under the MHRA's remit. Cell lines are covered by the Regulations and therefore come under the HTA's remit.

The HTA, as a proportionate regulator, does not intend to prevent what could in this particular case be life-saving therapy for such a patient. In light of this the HTA will not take any regulatory action in this particular instance. However, the HTA requests that you supply the it with an assurance in writing that the processing, labelling, storage and traceability requirements of the Human Tissue (Quality and Safety for Human Application) Regulations (2007), the 'Regulations', have been met.

It was suggested in April 2007, [redacted] that you apply either for a stand-alone licence or become a satellite of the University of Bristol, depending upon governance arrangements. I have checked all correspondence but I have not found any progress on this by Langford. As far as the HTA is concerned, therefore, Langford is an unlicensed premise. Since July

2007 it has been an offence to procure, process, test, store or distribute/import/export such cell lines for Human Application.

Under the Regulations, Langford is ‘storing’ and ‘processing’ cells for Human Application and therefore needs an HTA licence. Although the processing is being carried out ‘on behalf of’ the Clinic Barcelona (which, I understand, is licensed by the Spanish Competent Authority), such third party agreements are not applicable across borders from outside the U.K. Service Level Agreements are applicable, but these can only be set up between two licensed establishments.

Thus, licensable activities are being carried out on unlicensed premises. The HTA now requests that all licensable activity at Langford (processing, storage, etc) ceases until the Establishment has received an HTA licence. If tissues or cells are currently being stored on the premises alternative storage arrangements on licensed premises will need to be made until a licence is issued.

I hope this is clear. Please do not hesitate to contact me if you require further clarification.

Yours sincerely,