



**DEPARTMENT OF PATHOLOGY
UNIVERSITY OF CAMBRIDGE**

HUMAN TISSUE ACT (RESEARCH) COMMITTEE

Minutes of the meeting held on Friday 26 March 2010

Present: Prof Andrew Wyllie (Chair)
Ms Ann Cartwright
Ms Fiona Duncan
Prof Gerard Evan
Prof Bill Harris
Prof Chris Lowe
Dr Tom Matthams
Ms Frances McLoughlin (Secretary)
Prof Peter McNaughton
Dr Ruth Murrell-Lagnado
Prof Daniel St-Johnston
Dr Martin Welch

1. Welcome

Members were welcomed to the meeting. The Chair explained that this Committee was concerned with the University's research licence under the Human Tissue Authority for which the Chair was the Designated Individual (DI). There was an expectation that for the purposes of good management the DI would hold periodic meetings with the *Persons Designated* as holders of satellite licences under the University's research licence. A subsequent meeting would be held for those institutions that could not be present (Stem Cell and Biological Anthropology).

2. Current research licence holders and key responsibilities

(i) There were currently 8 institutions covered by the research licence as follows:

Pathology
Biochemistry
Physiology, Development and Neuroscience
Pharmacology
Chemical Engineering and Biotechnology (TCR site)
Biological Anthropology (Downing Street site)
Gurdon Institute
Centre for Stem Cell Research

(ii) Of those present all but the Gurdon Institute confirmed that they had holdings. At the time of applying for the research licence in 2006 the Gurdon Institute

wished to be included with a view to potentially holding human tissue at a later date but paid a reduced fee in respect of the licence cost.

- (iii) It was explained that the Human Tissue Authority retained a list of individuals with key responsibilities under the research licence. It was confirmed that in addition to the Designated Individual, whose responsibility it was to execute and oversee the implementation of the HT Act and HTA requirements, in each satellite site there was a *Person Designated*, currently the Head of Institution, who took responsibility for ensuring compliance at satellite level and for working within the regulatory framework. Each institution also needed a key contact who was responsible for the management of HTA operations. It was agreed that in each case this should be the Departmental Administrator.
- (iv) Members received a paper setting out the key responsibilities of the Designated Individual, Persons Designated, HTA Committee, individuals working with human tissue and institutional key contacts (Annex A).

3. Requirements for record keeping

- (i) It appeared that there were a number of practices for record keeping in place currently. An internal review of Pathology's holdings last year had raised questions about the detail needed. In general, individual research groups held very good records but in one case these were paper based and it was felt that they should be held electronically. Pathology was currently working on a template database for recording holdings.
- (ii) Practices in other departments varied but overall it was felt that thorough record keeping was in place (eg. Biochemistry). Previous advice had suggested that institutions should not duplicate effort if research groups were already holding good records but PDs needed some level of assurance that this was the case.
- (iii) It was agreed that a database could be set up to store records centrally but allow cross-platform access by a web browser which would allow all institutions to update their own records securely. Records could then be reviewed by the Committee as appropriate. Clarification was requested on how often the records should be updated. It was generally assumed that with the HTA requirement for recording dates of receipt and disposal for each holding, research groups would be updating their records on an ongoing basis. If these records were separate from a central database it would be necessary to know what the HTA expectation was for maintaining central records.

Action: Secretary

4. Induction and training of staff storing human tissue

This issue of induction for staff storing human tissue had been raised. It was agreed that institutions should include HT Act procedures within their induction programmes. The Frequently Asked Questions (Annex B), which had been prepared by the Departmental Administrator in Pathology were available on the University's HTA website (also maintained by Pathology) and would provide a

good introduction the Human Tissue Act. It was suggested that institutions should make the FAQs available as a paper document and those PIs with holdings should be required to read and sign the document with a copy being held as part of their training record.

Action: All sites

5. Process for annual internal review

It was expected that internal review of licensed sites should be undertaken annually. It was agreed that a programme for review should be put in place starting in Michaelmas term, after the database of holdings had been established. Pathology's internal review last year was based on guidance from the HTA and a similar approach could be used across all sites. The DI and Pathology's administrator would be involved in all reviews.

6. Fees for 2009/10

- (i) The licence fee for the current year was £12,300. It had previously been agreed that the cost be shared equally across all institutions covered by the research licence (with the exception of the Gurdon Institute which paid a reduced rate). This was on the basis that Pathology would manage all aspects of the licence including compliance, quality management and governance.
- (ii) The institutions present agreed to continue on this basis. The Gurdon Institute confirmed that it wished to relinquish its satellite licence.

7. Any Other Business

It was noted that following a review of Pathology's holdings last year University policies on blood transport and blood disposal were currently being drafted by the SBS Safety Officer.

8. Date of next meeting

It was agreed that the Committee should meet annually after the programme of internal review had been completed.

ADDITIONAL MEETING

Minutes of the meeting held on Wednesday 28 April 2010

Present: Prof Andrew Wyllie (Chair)
Prof Robert Foley
Prof Austin Smith
Ms Lynn Kennedy.

An additional meeting was held for those Persons Designated and Administrators who were not able to be present at the Committee meeting held in March. The agenda was the same

The following points were made:

- (i) There were currently no samples within Biological Anthropology that fell within the Act, but Prof Foley still wished his Department to remain a satellite site.
- (ii) The Stem Cell Institute did store samples that fell within the provisions of the Act. These are all logged into an electronic record that would be made available to the Licence Holder. Many were blood samples.
- (iii) Pathology would be in contact with the Stem Cell Institute and the Department of Biological Anthropology to ensure that record keeping in the satellite sites was mutually compatible. It would also give the satellite sites a statement of the costs of the Licence (shared equally amongst all Departments within the Licence).
- (iv) The Department of Pathology would inform the satellite sites of an internal review. In the meantime it was the responsibility of *Persons Designated* in each satellite to ensure that staff involved in storing material that fell within the Act had adequate training in the necessary documentation regarding time of receipt, identity code, place of storage and time of exhaustion.
- (v) The usefulness of the Frequently Asked Questions document prepared by the Department of Pathology's Departmental Secretary (Academic Services) was again noted.