

**Human Tissue Authority consultation on Code of Practice on the import and export of human bodies, body parts and tissue**

## **Introduction**

This paper provides a summary of the responses received by the Human Tissue Authority (HTA) to its consultation on its Code of Practice on the import and export of human bodies, body parts and tissue prepared under the Human Tissue Act 2004 (HT Act). It focuses particularly on the key messages which respondents to the consultation wished the HTA to consider when drawing up the final Code of Practice.

## **Background**

The HT Act received Royal Assent in November 2004 having received broad support in both houses of Parliament. The HT Act is a result of a comprehensive review of the law on the taking, storage and the use of human tissue and organs that followed post mortems.

Under the HT Act, the HTA is responsible for preparing a Code of Practice on “the import and the export of (i) the body of a deceased person, or (ii) relevant material which has come from a human body”.

The Code of Practice provides guidance and practical steps for establishments both licensed under the HT Act and for those not undertaking licensable activities under the HT Act, but nonetheless involved in the import and export of human bodies, body parts and tissue used for other purposes.

## **Process**

The Code of Practice on the import and export of human bodies, body parts and tissue was drafted by members of the HTA’s working group on import and export, who were drawn from research, academic and private sectors, as well as members of the Authority.

The first draft of the Code was presented to the Authority at its meeting on 18 April 2006. Members provided feedback and suggested revisions for the draft. Successive drafts were then prepared by the working committee and presented at Authority meetings in May, July, and September 2006. It was agreed at the latter meeting that, subject to proposed final changes, the draft could be released for public consultation the following month.

Consultation subsequently ran from 3 October 2006 to 12 January 2007. The consultation included a workshop of the HTA’s key stakeholders held at the British Medical Association in London on 5 December 2006.

The HTA considered very carefully the comments they received and made its decisions on the final content to be included in the Code of Practice based on the

responses to the consultation. The final version of the Code was approved at the meeting of Authority members on the 20 March 2007.

## Response

A total of 29 formal responses were received to the consultation. A wide range of stakeholders expressed their views, including health organisations, research organisations, universities, hospitals, Royal Colleges, museum bodies and individuals.

A breakdown of respondent type is shown below:

<b>Type of respondents</b>	
Health organisation	8
Research organisation	6
Royal College	3
Public – individual	3
Government organisation	3
Museum body	2
Medical school/university	2
Doctor (individual response)	1
Hospital – ENT dept.	1
<b>Total</b>	<b>29</b>

The overall response to the Codes was positive. While almost all respondents and workshop participants were able to suggest ways in which the Code could be improved, there was general support for the HTA to produce guidance in this area, and the process of consultation was considered to be valuable.

The HTA would like to thank all those who took time to respond to the consultation. The consultation responses formed a valuable and helpful contribution to the HTA's understanding and interpretation of its remit. Since a wide number of responses was received covering a broad range of areas, as expected, not all comments were taken into account.

## The key themes

The key themes that emerged from the consultation exercise were:

### *Underlying Principles*

There were several responses relating to the principles set out in the Code:

## **Justification**

The consultation draft stated that importers should be able to justify their decision to import tissue by demonstrating that comparable material is not available in their own country. Respondents asked why this should be a principle, what were the benefits and asked about its application to academic activity between linked establishments here and abroad. Questions were also asked about to whom the justification needed to be demonstrated.

The HTA considered that there are strong arguments to support the Code's line that tissue sourced locally should in general be preferred over importation, both to assure the integrity of material – in terms of consent and quality – up to the point of use, and to obviate the risk of exporting and re-importing material to circumvent the consent provisions. However, the HTA accepts that existing arrangements may already be in place with importers, such as collaborative research mechanisms – and this may be considered as justification for import. In addition, it is not the HTA's intention to impose additional bureaucratic burden on importers through onerous reporting and documentation procedures. The guidance in this section of the Code was therefore re-framed in this light.

## **Consent**

The issue of consent was raised in several responses. There was some confusion over when, or if, a licence is required for imports and how consent fits into this process. Further pointers were sought on how importers could or should demonstrate that consent had been obtained in other countries, given the differing ethical standards that may be in place. Imposing our standards of consent on other countries was seen as problematic and possibly even unethical. There was a general call for eliminating inconsistencies and for linking this Code more clearly to the HTA's other Codes of Practice.

The Authority reached a view on the primacy of consent within its guidance. The feedback to the consultation was addressed with a more consistent expression of the principle of consent within the Code. In the final version, the processes for obtaining informed consent appear in all three of its sections (licensed establishments; tissue banks; unlicensed activity) with practical guidance; the guidance on consent for non-licensed establishments now mirrors that for other licensed establishments; and the express requirements for tissue banks under the Regulations implementing the Tissues and Cells Directive which are more stringent, are now also included. In addition, where relevant, the Code provides cross-references to the HTA's other Codes of Practice.

## **Ethics**

The section on ethical approval in the consultation draft stated that requirements abroad should mirror those in England, Wales and Northern Ireland. Some

respondents sought clarification on how to set up (or pay for setting up of) a local ethics committee in a country where one does not exist. Questions were raised about what constitutes the suitable assurances that researchers should look for in importing tissue and who is responsible for deciding what they are. This latter point applied particularly to Part II of the Code, which covers non-licensed establishments, and came primarily from research organisations. Consent is stated as the key requirement of the ethical framework: further detail was sought on what other elements should be included.

The Code's references to ethical approval were redrafted to include further guidance on the setting up of ethics committees and their governance arrangements, together with the importance of working collaboratively to ensure that the necessary requirements are met.

## **Respect and dignity**

Although the HT Act is silent about respect and dignity, it was widely agreed that the Code should reflect these concepts as an underlying principle, as indeed the Authority had agreed when discussing the draft. A number of respondents asked for more guidance about what this would mean in practice.

The text in the final Code elaborates on the principle of respect and dignity, providing more guidance about how this should be enacted in practice.

## **Export**

Comments were made that the guidance should be made more explicit to state that importing material must meet standards in England, Wales and Northern Ireland, but that auditing exported material should remain the recipient's responsibility.

This has now subsequently been reflected in the guidance under the principle on Export.

## **Other themes which were raised in the consultation were as follows:**

### ***Structure***

There was some concern in the responses about repetition and that readers might need further help in being directed to the parts of the Code relevant to their practices.

The Code provides the explanation that as it is designed for different groups of users to consult, parts of its guidance are necessarily repeated under certain sections, as users may refer only to the section(s) which apply to their own

particular circumstances. The final version of the Code also includes a table of contents with clearer divisions and labelling of sections.

### ***Governance and Quality***

In terms of auditing, the participants at the workshop highlighted the need to be clearer about the role of the Designated Individual (DI): including what systems should be in place; what their responsibilities should cover; and how the practice works when there is no DI. The Code now explains the role of the DI in more detail and points to advice which the HTA is preparing for how to operate in the absence of a DI.

### ***The EU Directive***

Respondents requested that the Code provided greater clarity over the requirements and obligations under the EU Directives and the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

The Code contains a revised section on the EU Directive and now that the Regulations have been finalised, the licensing requirements are clearly set out in the Code.

### ***Scotland***

The position of Scotland arose both at the workshop and in written responses to the consultation: in terms of how the various requirements and best practice standards in the Code apply to Scotland. There was general concern among respondents that movement of bodies, body parts and tissue between Scotland and the rest of the UK would have to be designated as imports or exports and that the resulting administration would be burdensome, restrictive and financially damaging.

The HTA considered the position of Scotland in detail. As far as the HT Act's provisions dealing with import of bodies, tissue and organs are concerned, Scotland must be treated as another country and therefore the Act's provisions on import and export apply to Scotland in all cases except tissue for human application – which is covered by the Tissue Directive's provisions. This has been reflected accordingly in the revised version of the Code.